UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, and IRBESARTAN PRODUCTS LIABILITY LITIGATION	**CIVIL ACTION NUMBER: 1:19-md-02875-RMB-SAK Rule 702 Hearing**

Mitchell H. Cohen Building & U.S. Courthouse
4th and Cooper Streets
Camden, New Jersey 08101
Wednesday, September 18, 2024
Commencing at 1:39 p.m.

B E F O R E: **THE HONORABLE RENÉE MARIE BUMB, CHIEF UNITED STATES DISTRICT JUDGE**

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(Appearances continued onto next page)

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(PROCEEDINGS held in open court before the Honorable Renée Marie Bumb, Chief United States District Judge, at 1:39 p.m. as follows:)

THE COURTROOM DEPUTY: All rise.

THE COURT: Okay. Afternoon.

MR. SLATER: Afternoon, Your Honor.

MS. BROWN: Afternoon, Your Honor.

THE COURT: You can all have a seat. Thank you.

Okay. Are the witnesses ready?

MS. BROWN: Yes, Your Honor.

THE COURT: Okay.

MS. BROWN: We have today Dr. Ali Afnan for ZHP's cGMP witness.

THE COURT: Okay.

MS. BROWN: Dr. Afnan, should he come up, Your Honor?

THE COURT: Yes. Come forward, please. Thank you.

Are there any additional appearances I need to have on the record that weren't put on the record yesterday? I think you're all the same.

MS. BROWN: Not for us, Your Honor.

THE COURT: Yeah. Okay. Come forward.

MR. SLATER: Just my associate, Chris Geddis, is up here today. He wasn't here yesterday at the front.

MR. GEDDIS: Christopher Geddis, yes. Thank you.

THE COURT: Okay.

(Witness took the stand.)

THE COURTROOM DEPUTY: Good afternoon, Doctor. If you could please place your left hand on the Bible; raise your right hand.

Do you solemnly swear the testimony you're about to give in the case now before this Court will be the truth, the whole truth, and nothing but the truth, so help you God?

THE WITNESS: I do.

THE COURTROOM DEPUTY: Can you please state and spell your full name for the record.

THE WITNESS: Ali Mohammad Afnan.

THE COURTROOM DEPUTY: Can you please spell it.

THE WITNESS: A-L-I, M-O-H-A-M-M-A-D, A-F-N-A-N.

THE COURTROOM DEPUTY: Thank you.

THE COURT: Welcome. Have a seat.

THE WITNESS: Thank you.

THE COURT: Make yourself comfortable. If you could be careful with the chair. There's water there if you want it.

THE WITNESS: Thank you.

THE COURT: And you can bring the microphone closer to you.

THE WITNESS: Yes.

THE COURT: And keep your voice up. I am hard of hearing, so if you can keep your voice up, I would appreciate it.

THE WITNESS: Does this help, Your Honor?

THE COURT: Oh, good. Okay.

You may proceed.

MS. BROWN: Thank you, Your Honor.

Good afternoon. Alli Brown for ZHP. And I apologize to the Court and counsel, we do have copies of this presentation, and our colleague who is bringing them is stuck in traffic and should be here any moment. So as soon as she walks in, I will hand them to both. But with the Court's permission, we'll just get started.

THE COURT: Okay.

MS. BROWN: All right. Thank you.

ALI AFNAN, Ph.D., called as a witness for the Defendant, having been first duly sworn by the Deputy, was examined and testified as follows:

DEFENDANT'S EVIDENCE

DIRECT EXAMINATION

BY MS. BROWN:

Q. Good afternoon, Dr. Afnan. How are you?

A. Good afternoon. Thank you.

Q. Would you introduce yourself to the Court, please.

A. Yes. My name is Ali Afnan. I am the regulatory expert assigned to this project by Skadden.

Q. All right. Let's start by talking a little bit about your education and experience, okay, Dr. Afnan?

A. Yes.

So I studied chemistry in England, in University of Wales. And after my Bachelor of Science in chemistry, I went to University of Manchester to do a Master's in Science and a Ph.D., also in chemistry and process control.

Q. Okay. You said your Ph.D. is in chemistry and process control. Explain to us, what is process control?

A. So process control is the methodology and the science of how to control -- how to manage a chemical reaction to ensure that the materials that they are putting in are used up appropriately and that the product -- the end product is meeting specifications and is correct.

Q. And when you say "product," do you mean a pharmaceutical product like valsartan?

A. Absolutely.

Q. All right.

MS. BROWN: Your Honor, I do have a copy. Could I approach?

THE COURT: Yes.

MS. BROWN: Okay.

THE COURT: And one for the witness.

MS. BROWN: Yes. Thank you, Your Honor.

Dr. Afnan, here you go.

(Handing out documents.)

THE WITNESS: Yes. Thank you.

BY MS. BROWN:

Q. All right. Let's talk a little bit about your experience. Tell us, do you have experience in the pharmaceutical industry?

A. Yes. Collectively I have about 35 years of experience in the pharmaceutical industry. I started in ICI Pharmaceuticals where we were -- or the company at that time was developing products for hypertension, oncology, and some inhalation product. That firm or that organization became AstraZeneca, which is a better known name today in the U.S.

The work continued there, again, oncology, cholesterol, that the portfolio of drugs expanded. And then I left to join the FDA. And then I left the FDA to go into my consulting business, which is Step Change Pharma.

(Court reporter clarification.)

BY MS. BROWN:

Q. Let's talk a little bit, Dr. Afnan, about the work that you did at the FDA.

What part of the FDA did you work in?

A. So I was actually recruited by FDA to join their Center for Drug Evaluation and Research. The reason for joining was effectively in 2002, FDA had an initiative which was called the Drug Product Quality Initiative for 21st Century. I was recruited, brought over, and we moved over. And the job was to effectively look at the way FDA reviewed, inspected, and enforced policies related to drug manufacturing.

My job was to effectively look at the way FDA reviewed all applications in the Center for Devices, but as well as Center for Devices, some cross-sections into Center for Biologics Evaluation and Center for Veterinary Medicine and Office of Regulatory Affairs where the inspectors are.

Q. Dr. Afnan, we asked you to look at certain regulatory documents in this case; is that right?

A. Yes.

Q. Did you work with and look at those type of documents when you worked at the FDA?

A. Yes. That was the bread and butter of FDA. That is what FDA does.

Q. And in terms of the center of the FDA where you worked, is that the center that has oversight for pharmaceutical medicines like valsartan?

A. Yes. CDER manages all what we call small molecules, so all the drugs like valsartan, as well as some proteins, not vaccines effectively, but, yes.

Q. Okay. I don't want to spend too much time on it or embarrass you, but you did receive a number of awards for your work at the FDA; is that right?

A. Yes.

Q. And maybe just tell us about one or two that have the most significance to you.

A. So I'm really honored to have received the commissioner's

special citation for both inter and intra-center activities. So I worked across multiple centers of FDA. And then the other one is the IPS medal is given to one person a year, and it's for recognition of their contribution to the pharmaceutical industry.

Q. And you received that in 2012?

A. I received that, yes.

Q. When you say the commissioner's award, is that the commissioner of the FDA?

A. Yes.

Q. What about publications? Do you have -- as it relates to what we asked you to do in this case, do you have any relevant publications?

A. So when in industry, I published some documents which were, you know, I have more than 30 documents, 30 publications. If you look at my list of presentations, public presentations, it would be hundreds probably.

In Pharma Manufacturing, I had a monthly article that I would write, and it was all about FDA oversight, FDA enforcement, and industry's response to those in Pharma Manufacturing. And ever since then, I have been an editor of the Contract Pharma Magazine, which looks at contract manufacturers.

Q. When did you leave the FDA, Dr. Afnan?

A. March 2010.

Q. And you mentioned you've been doing some consulting work since that time; is that right?
A. Yes.
Q. And just describe to us briefly what you've been doing since 2010 in your consulting world.
A. So in my consulting world, I have been looking at or working with pharma, looking at developing manufacturing processes, but mostly regulatory. You know, how do you -- particularly if there is a novel method of manufacture, how do you document that and present to FDA for approval. I have also been working with firms who get into trouble with FDA with 483s and warning letters, and effectively looking at --

THE COURT: In trouble with FDA with what? Oh, warning letters.

THE WITNESS: Warning letters, yes. They get into trouble for whatever reason. So it's compliance and process improvement and registration with FDA.

BY MS. BROWN:
Q. All right. Let's talk, Dr. Afnan, about what we asked you to do in this case.

Would you describe to the Court what your assignment was as it relates to your expert role here?
A. I was asked to effectively respond and opine to plaintiff experts Dr. Najafi, Dr. Plunkett, Dr. Hecht, and Ms. Bain.
Q. All right. And as it relates to your opinion and response

to the plaintiffs' experts, did we work together to put together sort of a summary of those opinions?

A. Yes.

Q. All right. Explain to us, at a high level, what is your key opinion in this case?

A. So the plaintiff experts opined that ZHP violated the cGMPs. At high --

Q. Can I stop you right there?

A. Yes.

Q. Because a lot of what you're going to talk about uses a lot of letters for abbreviations, right?

A. I apologize.

Q. Okay. So can you just -- what is a cGMP?

A. So GMP stands for good manufacturing practice.

Q. Uh-huh.

A. And good manufacturing practice is about 47 pages. It's not that bad. It's actually 47 pages in the published Code of Federal Regulations. The C stands for "current" good manufacturing practice. And so the plaintiff experts say -- and this is about, you know, effectively that if you were to distill the GMPs into two sentences, it would be: "Follow written procedures and have written procedures."

So plaintiff experts opined that ZHP violated cGMPs. In my review and analysis of their findings, their reports, and analysis of the regulations and the regulatory record, I

disagree with them, because ZHP did conduct a risk assessment. It was appropriate. They did appropriate testing, the testing that they have committed to FDA that they would do. And valsartan was not adulterated prior to 2018 warning letter.

And when they did find NDMA in their products, they swiftly responded and reacted, informed the FDA into action.

(Court reporter clarification.)

BY MS. BROWN:

Q. Dr. Afnan, have you had the opportunity to review some of the motions that have been filed by the plaintiffs' counsel regarding your proposed testimony?

A. Yes. In March of -- in March there was a motion to exclude those statements, paragraphs of mine, that are potentially legal definitions, right.

Q. What was your understanding about -- we have it on the slide -- this sort of first motion to exclude, what was your understanding of the result there?

A. So the result was that the Court effectively agreed with five paragraphs to be excluded.

Q. Okay. And your report is approximately how many paragraphs?

A. It's 212. It's over 200.

Q. All right. Did you come to learn about a second motion that plaintiffs filed regarding your proposed testimony?

A. Yes.

Q. And what do you understand to be the subject of that motion?
A. So I understand that the motion is that all of my testimony should be excluded because it relies on Dr. Xue.
Q. Who is Dr. Xue?
A. Dr. Xue is a synthetic organic chemist who is a university professor at University of Maryland, native Chinese speaking, and he was also the defense expert as an organic chemist.
Q. Okay. Do you understand Dr. Xue to have written a report, an expert report in this case?
A. Yes.
Q. Did you review it?
A. I looked at it the night before I submitted my report.
Q. Okay.
A. That's when I received it.
Q. Was that the first time you received Dr. Xue's report?
A. Yes.
Q. Okay. Had you already formed your opinions by the time you received Dr. Xue's report?
A. Yes.
Q. Did you cite Dr. Xue's report in your own expert report?
A. Yes. I had developed my own opinion about -- all my opinions in the 212 statements were there. When I read his report that evening, it was a case of, wow, he has the same understanding and the same opinion on a certain issue, and so I

referenced to him in two paragraphs.

Q. Okay. Do your opinions in this case rely or depend exclusively on anything Dr. Xue said in his report?

A. No. I had no interaction with Dr. Xue, and everything in my report is my work.

Q. Okay. If you did not rely on Dr. Xue, then, Dr. Afnan, I want to talk a little bit now about what you did do and what you did rely on, okay?

THE COURT: Could you just tell me what you said in your report? Did you use the word -- what is the basis of the motion?

Can I see the report?

MS. BROWN: Yes, Your Honor. We have a copy right here.

May I approach?

THE COURT: Yes.

Can you direct me to where it's at?

MS. BROWN: Yes. There are two paragraphs -- the paragraphs that cited Dr. Xue, Your Honor? Is that what you're asking?

THE COURT: Yep. Yes.

MS. BROWN: Yes. We'll grab them right now.

I believe it's one...

(Counsel conferring.)

MS. BROWN: It's 141, Your Honor. And --

THE COURT: Can I keep this?

MS. BROWN: Yes. And 190.

THE COURT: Okay. Just give me one second.

MS. BROWN: Of course.

(Pause.)

THE COURT: Okay. All right. Thank you.

MS. BROWN: Sure. May I proceed?

THE COURT: Yes.

BY MS. BROWN:

Q. And as the Court pointed out, Dr. Afnan, there are two places in your expert report, paragraphs 141 and 190, where you cite Dr. Xue.

A. Yes.

Q. Correct?

All right. And I want to talk about what you are relying on, if not Dr. Xue, for the bases of your opinions, okay?

A. Sure.

Q. Tell us a little bit about your methodology, how you approached your assignment and what you looked at and are relying on here.

A. So my assignment -- upon getting my assignment, I received the plaintiff experts' reports. I also received their testimonies as well as ZHP's employees' depositions, testimonies. I reviewed the plaintiff experts' reports,

analyzed them, then looked at the regulatory requirements, which I was familiar with, but it was a case of let's go back to the written record, the regulatory record, compare the two together, and effectively developed my understanding based on what the regulation and the requirements as stipulated by FDA are and what ZHP had done and what the plaintiff experts were saying. So it was analyze what was stated by the plaintiff experts, analyze what is in the regulation, and look at what had taken place.

Q. And when you say "what had taken place," did you look at the regulatory record as it relates to submissions ZHP and some of the other manufacturers submitted to the FDA?

A. Yes. And included in that were the inspections and also the inspection records.

Q. Okay. And did you also consider deposition testimony that was relevant to the issue you were analyzing?

A. Yes.

Q. Okay. Let's talk about some of your findings based on the regulatory record, because I want to explore with you briefly what support you have for these findings, if not Dr. Xue, okay?

A. Yes.

Q. Help us understand what the regulatory records show when you reviewed it in furtherance of your assignment.

A. So the regulations require that when a firm is manufacturing an active pharmaceutical ingredient, API, or we

call it alternate drug substance, the firm needs to consider reasonable consideration to the potential of formation of impurities. But it's not a case of go and look at every impurity which is formed. The regulations allow a little freedom in the sense of saying if you are not expecting anything untoward, look for impurities, and effectively your impurities should be below a certain limit. If they're above, you need to identify them. So every product has known and unknown impurities.

So what I found was that ZHP did --

THE COURT: Wait. Can you say that again, please?

THE WITNESS: So there are -- the regulatory requirements are that you should look at -- or the firm should look at impurities in a drug substance. But they're not expecting the firm to look for all the unknowns or even things they're not expecting. The impurities that come and the impurities that are there, Your Honor, they come at different concentrations, and the regulations require that you can actually not identify those below .1 percent concentration. But the sum of all the unknowns cannot be greater than 2 percent.

And ZHP looked at this information and did the evaluation, and their product was within those specifications and requirements.

THE COURT: Got it.

THE WITNESS: Okay.

The second was that as ZHP did these changes to their process, they documented it, and they submitted it to FDA for FDA review. In fact, no firm is allowed to ship product unless it has approval for that product. And the drug product manufacturers, the finished-dose manufacturers, would not have accepted the consignment of active ingredient from ZHP unless it was approved by FDA.

So ZHP find all these changes with FDA which got its review, was reviewed. There were even a couple of times interactions between FDA and ZHP, and then FDA inspected the facility I think three times, which was full inspection, and I'll come to what inspection is, what's full, what's abbreviated.

ZHP then actually informed the drug product manufacturers that I have done these changes and here is the approval by FDA. And that's -- the firms also audited ZHP.

One of the requirements of GMPs is that the drug, the finished-dose manufacturers have a contract with the supplier and that they audit them on a frequency of maybe once a year or twice a year to see that the firm -- in this case ZHP -- is still compliant with GMPs.

And over the years I think there were, I don't know, there were 50 clients, so that would be about minimum 25, 30 audits per year, in addition to FDA inspections.

And then lastly, the regulatory record where the FDA statements, which effectively said industry didn't know about the formation of NDMAs or the method for detection of NDMAs. FDA didn't know about the formation of NDMAs or the detection of NDMAs.

BY MS. BROWN:

Q. I want to follow up on a couple of things you said --

A. Yes.

Q. -- before we talk briefly about what the record shows on each one of these points.

A. Yeah.

Q. One of the things you spoke a bit about there, Dr. Afnan, are changes to the manufacturing process that ZHP put in place. Do you recall that testimony?

A. Yes.

Q. Was it the case that ultimately those changes were found to have been what led to the formation of NDMA and NDEA?

A. Yes. Once -- the answer is yes.

Once ZHP knew that NDMA was in its product, which was in June of 2018, they quickly went back and looked at the process and discovered where NDMA was produced. And, yes, it was due to those changes.

Q. Okay. And are those the very changes that the record shows were submitted to the FDA in real time?

A. Yes. They were submitted -- they were -- they developed

those processes in-house. They test it. They then submit it to the FDA and got approval from FDA.

Q. Okay. Thanks, Dr. Afnan.

I want to talk -- I want to quickly move through each one of these so we can just understand your methodology and the basis for these opinions.

So the first opinion you had listed was that ZHP was required to and did evaluate expected risks.

First of all, is this opinion of yours based any way on anything Dr. Xue said or wrote in his report?

A. No. I don't think even Dr. Xue would know about these regulations.

Q. Okay. The Judge asked some questions about following up on the concept of impurities in a medicine. Do you recall those questions?

A. Yeah.

Q. Do all medicines have impurities?

A. Yes.

Q. And are there regulations that govern those impurities?

A. Yes.

Q. Are there regulations that govern a manufacturer's responsibility to evaluate whether there will be impurities and what they are?

A. So a chemical reaction will always have impurities. So the expectation is to -- to look for unknown impurities, but

there is also an expectation to look if there is likely to be any bad impurities. But it's all based on C in the GMPs, the current knowledge at the time.

Q. Is there a guidance that applies to a manufacturer's cGMP responsibilities as it relates to evaluating expected risks?

A. Yes; another set of acronyms.

Q. Okay. Tell us what they are.

A. There is ICH Q3A.

ICH is International Committee for Harmonisation. It's a committee set up by FDA, European Medicine's Agency, so FDA, Europeans and Japan. And all the other regulatory agencies worldwide also follow this.

This is set up, and industry is an observer at ICH. So they have a say, they have an input. So ICH has four classes of guidances. And one of them are all to do with quality. So Quality No. 3, that's when they issued it, is ICH Q3. There is an A, a B, a C. And so A is for drug substances, which is the subject of this case.

So Q3A very specifically says: "The applicant should summarize the actual and potential impurities most likely to arise." And then it says the discussion can be limited to the impurities that might reasonably be expected based on the knowledge of the chemical reaction and conditions involved.

Q. And now how does that guidance inform your evaluation of the opinions of plaintiffs' experts in the case?

A. So ZHP actually did adhere to Q3A. In fact, FDA requires that firms be compliant to Q3A. And, you know, finished-dose manufacturers need to be compliant to Q3B as well as A. A for receipt of materials. B for making their drug product.

So, yes, they did. And if you look at what this requires is to look to identify -- not identify, to actually find impurities. The ones which are above a certain limit need to be identified. And the ones which are below a certain limit can be ignored, but the totality of the unknowns that are being ignored cannot go above 2 percent.

Q. Okay. And is this another citation to the ICH guidance regarding the percentages you were just discussing?

A. Yes.

Q. Okay. And based on your review of the regulatory record, did ZHP comply with this requirement of an identification of an impurity above .1 percent?

A. Yes. They -- so there are known impurities in valsartan which is effectively defined that you need to look for these. You know, so if I decided to make valsartan API tomorrow, there are certain impurities that I know I have to look for, okay. So today actually I would have to look for nitrosamines as well.

THE COURT: And how do you know that?

THE WITNESS: It's all listed, Your Honor, in a monograph which is issued by United States Pharmacopeia, USP.

And that lists the test methods as well as the actual impurity, the known impurities would be in USP.

THE COURT: So at the time of this, nitrosamine was not listed in the USP?

THE WITNESS: No, no.

THE COURT: It would be today is what you're saying?

THE WITNESS: It actually still is not in the monograph for valsartan. So now what the USP says is you should look for nitrosamines. So both FDA and USP changed some of their guidances upon the finding of nitrosamine in valsartan.

THE COURT: So it is listed in USP now?

THE WITNESS: It is listed not in the monograph. It's listed separately.

THE COURT: Oh, okay. I got it. Okay.

BY MS. BROWN:

Q. And just to follow up on that, Dr. Afnan, today does FDA and USP recognize the need to look for nitrosamines?

A. Oh, yes, very much. In fact, at the beginning of this month, FDA issued -- revised, not had issued, it revised its guidance on nitrosamines which were issued in I think 2019 about what to look for, what the levels are, what you should do with each batch, yes.

Q. And prior to 2018, was there such a guidance?

A. No.

Q. Let's talk about number 2 on your list, FDA reviewed, approved, and inspected ZHP's processes and facilities.

Let me ask you first: Is there anything about this opinion you have that is based on Dr. Xue?

A. No. This is entirely based on my nearly ten years experience of FDA and about 20 more years in industry working with firms and indirectly engaging FDA.

Q. We spoke a little bit earlier about manufacturers like ZHP submitting information to the FDA. Do you remember that?

A. Yes.

Q. As it relates to the opinions about process changes that you have, help us understand what information was provided to the FDA and how that informs your opinion.

A. Okay. So when a firm, so an API manufacturer, a drug substance manufacturer, you know, like ZHP --

Q. And API is active pharmaceutical ingredient?

A. Active pharmaceutical ingredient.

Q. Okay.

A. When an active pharmaceutical ingredient manufacturer, particularly in the generic world, wants to sell a drug substance, they prefer to document it in a Drug Master File, a DMF. They file the Drug Master File with FDA. FDA receives it, lists it, but doesn't do anything with it. Then when the firm tries to sell that drug substance to a drug product manufacturer, a finished-dose manufacturer, they refer to it in

their application ANDA or NDA, and then FDA reviews the DMF. So this work, the entire process in 2010, was submitted to FDA which said exactly how ZHP was going to manufacture. So that was approved. So the DMF was approved.

Every change that is done to the process needs to be submitted to FDA. Even if there are no changes done annually, there has to be a report to FDA that I have not made any changes to my process.

Q. And who at FDA, to your knowledge, would have been reviewing these changes and these submissions?

A. So the DMF would have been received by the group at FDA. I personally know some of them. They would have reviewed it, and then every time a new drug product manufacturer, a finished-dose manufacturer would submit it, the DMF would be referenced by some of those reviewers. In fact, in some of the documents that we have, I know the people who are still in FDA. I used to work with them.

Q. Does FDA employ chemists and other scientists who review these submissions?

A. Yes. Actually, to be in the review divisions and the biggest office within Center for Drugs are reviewers. The job title of everyone is chemist. And they are chemists, and they are organic chemists. In fact, Dr. Gottlieb, the commissioner also when he put out the press release did say that our organic chemist did look at this process and didn't identify it. So,

yes, they are.

Q. Did you review, as part of your expert work in this case, the relevant submission ZHP made to the FDA regarding the processes that ultimately were discovered to have led to the formation of NDMA and NDEA?

A. Yes.

Q. Okay. And how does this inform your opinions here?

A. So as -- so looking at it, FDA -- ZHP did not hold anything back from FDA at any time. Everything was submitted -- everything was submitted with evidence, right. So it wasn't a case of I'm changing this process. It was submitted with we have done these studies and based on these studies and based on these effectively controls, we are bringing about a process change.

If -- may I take a minute to explain something?

THE COURT: Please.

THE WITNESS: So within a firm, according to the cGMPs, you have to have a process called "change control." And change controls are reviewed every time investigators are on site.

So here what we see is effectively the review process. So I submit a document, or ZHP submitted a document to the reviewers at FDA who are all -- if you're a reviewer, you're a Ph.D. You're not a -- you don't have a degree, you have a Ph.D. They then get verified by investigators who come

on site to make sure that what you're doing is correct. And one of those oversight activities is to look at the change control procedure. And a change control says you can't change anything unless it has been reviewed and effectively the change is controlled.

So all of those submissions to the FDA would have resulted, because they can't change till the FDA says you can change, they would have resulted in a change control internally which would have been approved by quality before implemented.

BY MS. BROWN:

Q. Okay. Did the FDA inspect ZHP's facilities?

A. Yes.

So FDA inspected Chuannan, which is where this active ingredient was manufactured. And on the screen you see PAI and, you know, surveillance. So PAI stands for pre-approval inspection. Pre-approval inspection is when you have submitted a document which we saw on the previous screen to the FDA and you say I would like to do these changes. So FDA reviewers would review this. They will then request the investigators to go and verify certain things. And those certain things are the analytical methodology, the quality system, and also the specific changes which have been stated by the firm. Those changes will not have happened yet, but they would be ready, ready to go.

So these are pre-approval inspections. And

surveillance means I'm coming to see what you're doing. So these would have been week-long inspections. And as you can see, it says "no action indicated." NAI is a classification by FDA which says, I did not find any objectionable incident of anything. There is nothing.

Q. Now -- and we do see by August of 2018 there is official action indicated. What was the cause of that?

A. This was it says for-cause, which means FDA was there for a specific purpose and reason, and that is post finding of NDMA.

So ZHP identified -- you know, NDMA was identified. ZHP informed the FDA. FDA then came for an inspection. This is two months after they informed the FDA that we have NDMA.

Q. Okay. And did you also review inspections of a different facility where finished doses were being made?

A. Yes. It's again exactly the same, and the official action indicated, 2019. Again, this is post NDMA finding.

By the way, voluntary action indicated means I have some observations, but it's really voluntary whether you handle it or not, however industry deals with it.

Q. And based on your review of the record and the regulations and your experience, what is the purpose of these inspections? What is FDA doing when it comes into ZHP's facilities?

A. So FDA, you know, surveillance inspections that was on the screen, for example, FDA defines it's a system-based oversight.

So they expect a system to be in place at the pharma company to assure quality. And this system has six subsystems, and those are effectively the quality, the QA organization, the quality assurance organization; the facilities and equipment, how do you clean it, how do you maintain it, how do you install it, how do you remove it, so on and so forth; materials; production, packaging and labeling, you know, how do you ship it, who has control; and lab controls and testing.

And what FDA does in surveillance inspections is at least four of those, two of which have to be -- two of the four have to be quality and lab are inspected.

Most of these, in fact, I think most of the inspections all six were hit. All six were reviewed.

The purpose of these is to --

THE COURT: How can you know that?

THE WITNESS: So looking at the inspection report and looking at --

THE COURT: Is there a box they check off or something?

THE WITNESS: So what they do, the investigators have a software on their computer which actually tells them look at this, look at this, look at this. And any observations it automatically populates it to a Code of Federal Regulation citation.

So if they don't like, for example, the way they have

investigated a complaint, when they say investigations, it automatically populates that line. And that's what you see, Your Honor, in the warning letter, the bold lettering is coming from there.

BY MS. BROWN:

Q. So does that mean, Dr. Afnan --

MS. BROWN: I'm sorry, Judge, did you have a follow-up?

BY MS. BROWN:

Q. Does that mean when you look at the documents from these inspections, you can tell which of these categories they were looking at?

A. So when you look at it and, you know, the name of the inspector is there, the duration is there. The way FDA inspections work is FDA says look at the procedure, look at the facility, look at the actual room where an event takes place and then look at the evidence. The evidence is show me the documents that is there. And they're there. I mean, the last establishment inspection report is very detailed as to what they looked at.

They don't -- they don't say, for example, I looked at materials and, in fact, in the establishment inspection report they say I looked at materials and I have no objections. In the 483s, they don't say I have no objections. And really, the inspections are designed to make sure the firm, all firms,

any firm, their feet are held to the fire of you need to be compliant with GMPs.

Q. So when the FDA is inspecting, they're inspecting with conformance with cGMP in mind?

A. Yes. And it's very easy -- I do this, I've been doing this now for many years -- it's very easy to actually very quickly, within the first two days, know which section -- which one of those subsystems has a problem. And the way you do this is you ask for certain documents, one of which are investigations, deviations, market complaints, out of specifications, and immediately they will pull everything out.

Q. Let's move quickly through the other two observations or findings from the regulatory record.

Your list included that ZHP disclosed these processes not just to the FDA but also to the finished-dose manufacturers or the companies that took ZHP's API and made it into medicine tablets. What is that opinion based -- first of all, is that based on Dr. Xue?

A. No. Again, I'm -- you know, I didn't look the evening I received the report to see what his reliance list was. And anyway, it wouldn't have made sense to me because it would have just been a page after page of numbers. No, it's not. No, it's not based on that.

Q. Did you review documents that support your opinion that ZHP disclosed these process changes to finished-dose

manufacturers?

A. Yes. So there were change controls or change requests which were sent to drug product manufacturers. In addition to that, because this was tied to a Drug Master File, they would have had to inform them that there was a change to the Drug Master File. And if I look online at the Drug Master File and I have no authority to dig into the master file, I would have seen that there was a change to the process. So, yes, it was conveyed.

Q. All right. Do finished-dose manufacturers, and did you see evidence of this in the regulatory record, do they inspect and audit ZHP?

A. Yes. I mean, this was -- this is a -- this is a cGMP requirement on the drug product manufacturers to audit their suppliers. So there would be hundreds. You know, in eight years, there would have been hundreds of audits performed by the customers.

Q. And did you review those generally in terms of their findings?

A. So they -- the statements are that there was no issue, no finding. I mean, if there was an issue and it was a serious issue, the drug product manufacturers would have moved -- you know, would have looked for an alternative source. They didn't.

Q. Finally, Dr. Afnan, your opinion that ZHP complied with

cGMP was supported by the FDA's statements; is that correct?

A. Yes.

Q. Is there anything about these FDA statements for which you are relying on Dr. Xue?

A. No.

Q. Okay. We have some of them that we called out in the next couple of slides.

Tell us what these statements are and how they inform your opinion.

A. So FDA press releases or particularly these two issued by the commissioner, this is not the, you know, this is not the commissioner sitting in his office and deciding I'm going to do a press release. So these press releases, and I was part of issuing a press release when Dr. Gottlieb was a deputy commissioner, it's very rigorous, very detailed, and it truly is from a broad spectrum of FDA offices and employees. So it goes through many iterations and reviews and making sure everything is correct, so on and so forth.

These -- both of these effectively FDA says the presence of NDMA was unexpected. Neither industry nor FDA knew about the formation of NDMAs or how to even detect them.

In fact, in one of the --

THE COURT: That's how you interpret -- that's --

THE WITNESS: Yes.

THE COURT: That's what you're saying by unexpected,

right?

THE WITNESS: Yes.

THE COURT: Okay.

THE WITNESS: That's -- the highlighted text is actually from the press release.

THE COURT: Okay.

BY MS. BROWN:

Q. So this, we're looking at a press release from the FDA from July of 2018 that says, "The presence of NDMA was unexpected" and thought to be related to what we're talking about, changes in the process, correct?

A. Yes.

Q. And we have another one here from just about a month later; is that right?

A. Correct.

Q. And this one again says that "it was not indicated that NDMA would occur," correct?

A. Correct.

Q. And this also talks about NDMA's properties making it difficult to find, correct?

A. Yes.

Q. Okay. We have another one here. This, I guess, is more from that August press release, correct?

A. (Witness nodding.)

Q. And it says: "Before we undertook this analysis, neither

regulators nor industry fully understood how NDMA could form during this process."

How did that inform your opinions about whether or not ZHP was complying with its current good manufacturing practice's responsibilities?

A. I -- I mean, that's in black and white. This is the FDA commissioner representing the FDA saying neither regulators nor industry fully understood how NDMA could form during this process. They didn't know that. The organic chemists at FDA had reviewed the process. The drug product manufacturers had exposure to the process. ZHP's scientists, chemists had looked at this. They didn't expect NDMA.

Q. And this is more -- this is now several months later, another release from January of 2019, and it reiterates some of the same language; is that right, Dr. Afnan?

A. Yes. Yes.

Q. Before we undertook this investigation, again, they say neither regulators nor industry understood how this could happen, correct?

A. Correct. They -- yes.

Q. As far as --

THE COURT: Can you just talk to me about -- so going back to the beginning of your testimony, you were talking about the industry practice, if I understood you correctly. The industry practice is that you test for what might be a

reasonable risk. I mean, you don't test for the unknown. You don't test for, you know, things you can make up in your mind or whatever, but you test for what might be known. That's an industry standard? Talk to me about that more.

THE WITNESS: That's, yes, Your Honor, that's an industry standard as well as an FDA standard. So FDA says look for potentially what's likely to form. So that comes from understanding your manufacturing process of what is likely to happen. And --

THE COURT: And where is that? Is it in the regs? Where is that?

THE WITNESS: So this is --

THE COURT: Or is it just understood that that's in the industry?

THE WITNESS: No.

THE COURT: Where is that?

THE WITNESS: It --

THE COURT: Because as I'm understanding it, the FDA doesn't require, as I'm understanding it, manufacturers to go looking for something that no one would expect.

THE WITNESS: Correct.

It's in ICH Q3A and in ICH Q3B. 3A is for drug substance. It says, "actual and potential impurities most likely to arise."

THE COURT: Oh, "reasonably be expected."

THE WITNESS: Yeah.

THE COURT: Okay. That's the standard?

THE WITNESS: Yes.

THE COURT: Okay.

MS. BROWN: And, Your Honor, I think you found it, it's slide 13. We just went back to it if that's --

THE COURT: Yeah. I just found it. Thank you.

MS. BROWN: Okay. Okay. Great. Sure.

THE COURT: Okay. Go ahead.

MS. BROWN: Okay. Thank you, Your Honor. I'll just go back to where we were.

BY MS. BROWN:

Q. And I guess just to follow up on what the Judge just asked, when you evaluate these statements from the FDA that say publically regulators, industry didn't know, how do you evaluate that in context with the ICH obligations to test for what is reasonably expected?

A. Can you ask that again?

Q. Bad question? Yeah.

A. Yeah.

Q. I'll try again.

A. It went around my head.

Q. Yeah; no. It was too wordy.

I guess what I'm asking is just to follow up on what the Judge was asking is sort of how were these statements from

the FDA, how does that fit into your opinion that ZHP was complying with the ICH obligations?

A. Thank you.

THE COURT: May I ask a different question?

MS. BROWN: Maybe better, please, Judge, yes.

THE COURT: Who determines what is reasonably to be expected?

THE WITNESS: So who determines what's reasonably expected is --

THE COURT: To be expected.

THE WITNESS: To be expected, it's a case of it comes from the experience of the chemists who are developing the process and what is the current understanding of the science at the time when they're doing this.

You know, we have been through multiple different types of drugs where post approval we come to realize that this is not a good practice or it is a good practice.

So effectively there is a -- if I go back to Q3A and look at that, this is a case of saying look at what is "reasonably," and you say what is reasonable, and that goes back to the knowledge and understanding of the chemistry.

So how that works in reality is that if you are making a vaccine, for example, like the COVID vaccine, you will not be, you know, you'll be a Ph.D. biochemist, but you will not be looking at the valsartan process. And if you're a

valsartan chemist, Ph.D. chemist, you wouldn't be looking at the COVID vaccine because they are two different, very different types of processes that have very different methods of manufacturing. So it goes based on, effectively, experience.

The other way this gets addressed, the reasonable, is the number of different people who get to review an application or a process before it's even presented to the regulator. So to do, for example, this particular process, the change, there was a nine-month study carried out at ZHP to see if we do this change, what would happen. So there was a nine-month study done by a multitude of people reviewed by multitude of chemists, and it's literally, you know, different people have different opinions, different ways of looking at the problem, and that's how you come to the point of saying should I be looking at this unknown or not.

THE COURT: But who is the final arbiter of what is reasonably to be expected or what is reasonable to look for? Is it those, you know, on the ground in the industry doing it, or is it in consultation with the FDA, or is it just the FDA and their chemist? Who's the arbiter of that?

THE WITNESS: It's both. So industry would look and would eventually come up with an answer which is then presented to FDA.

Now, the way FDA would review this process is that

they would also, you know, again, when it goes to a reviewer, it's not only one reviewer who reviews. So the reviewer would review that, and they have the option to go outside of FDA or outside of their immediate office. You know, they could go to, for example, somebody else in Center for Biologics or even any university. Or --

THE COURT: The FDA has that option?

THE WITNESS: Yes, the FDA has that option.

And FDA also has access to the entire published world, you know, they've got access to the libraries worldwide. But FDA also can go back and ask questions from the industry saying did you look at that, did you look at that, what is this, what's that, what's the other?

THE COURT: And once they're satisfied, is that it?

THE WITNESS: They would approve. But you have to continuously look at, effectively, market complaints, what's the response coming back from the market. And those need to be taken into consideration. And they may result in changes based on, you know, a patient goes and says I take this and my heart palpitates and goes up. That has to be addressed.

THE COURT: Thank you. Okay.

MS. BROWN: Thank you, Your Honor.

THE COURT: Sorry, Ms. Brown, go ahead.

MS. BROWN: We're almost done.

BY MS. BROWN:

Q. Two more things I want to ask you about whether you considered in forming your opinions.

Are you familiar with a warning letter ZHP received after the discovery of nitrosamines in November of 2018?

A. Yes.

Q. Did this warning letter find cGMP violations?

A. Yes.

Q. Do you agree with the FDA's finding in November of 2018?

A. Yes.

Q. Okay. How do you square this warning letter with your opinion that prior to this time period ZHP was in compliance with cGMP?

A. So this warning letter was issued in November of 2018, after ZHP had informed the FDA that there is nitrosamine in the product. It is after the product was recalled and, you know, theoretically, there shouldn't have been any active pharmaceutical ingredient in any market. And this is a finding of November 2018, after FDA had inspected them, issued Form 483, effectively, inspection observations, had received a response and had now issued this warning letter. So it's the moment -- it's an event in time.

Q. In your opinion, based on your review of the record and your experience, does this warning letter and these findings in November of 2018, do they negate or change the FDA's findings years earlier when they inspected for cGMP and when they

approved the DMF and when they had other correspondence with ZHP?

A. No, it does not negate. The FDA has the option to do that if FDA wanted to. They would withdraw the approval. FDA did not.

Q. Okay. Are you familiar, Dr. Afnan, with plaintiffs' experts' opinions in this case about a July 2017 email written by a ZHP scientist, Dr. Jinsheng Lin?

A. Yes.

Q. And what is, based on your review of the record, plaintiffs' experts' opinion about this email?

A. So the expert opinion, the plaintiff expert opinion is that this email identified in July 2017 presence of NDMA in valsartan and informed the management.

Q. Okay. Based on your review of the totality of the record, do you believe the record supports that opinion?

A. No.

Q. Why not?

A. So this is a -- this is a difficult-to-read English translation of a Chinese email. So I don't read any Chinese. The English is difficult to read. And there are different -- there are different translations of this.

This email with an attachment is referring -- and I've extensively looked at the attachment. The attachment is a patent, and this email is talking about the potential formation

of a nitroso compound similar to Impurity K in a different drug, irbesartan.

Now, if I may explain what Impurity K is.

Q. Yes, please.

A. Impurity K is one of the known impurities that valsartan manufacturing needs to look for. It's a nitroso compound. And they've known about it or we've known about it for many years and therefore it's on the USP monograph. So the nitroso referred to in the email is similar to Impurity K, and it says that it can form in production of irbesartan.

Q. Okay. Is there anything else you're relying on in relation to evaluating plaintiffs' opinion that this email shows that ZHP was aware of NDMA?

A. No. I actually spoke to Ms. Jucai Ge.

Q. Who, as it relates to this email, who's Ms. Jucai Ge?

A. She is the recipient. She is the person to whom this email was sent in Chinese.

Q. Uh-huh.

A. And I spoke to her, and I asked her whether this email states that, you know, did it inform her that there is nitrosamines present. And she said, no, I've spoken to the gentleman who wrote it as well, no, it doesn't. And I read it, and it doesn't. And then I've read her sworn testimony where she was asked if this relates to it, and the answer was no.

Q. Okay. When we started out, Doctor, we identified the two

paragraphs of your report that referenced Dr. Xue. Do you recall that?

A. Yes.

Q. And one of the paragraphs, paragraph 190, actually talks about this email, correct?

A. Yes.

Q. And in this paragraph 190, you do refer to Dr. Xue's report.

A. Yes.

Q. Is your opinion about whether or not plaintiffs' experts' interpretation of this email is supported by the evidence or not, is that opinion based on Dr. Xue?

A. No. And it cannot be because I spoke to Jucai Ge about this email, and I could not have arranged to talk to her that night and then change my report and so on and so forth. So, no, it doesn't.

Q. Had you formed your opinions about this email prior to reading Dr. Xue's report?

A. Yes. I had formed my opinion. I saw his report, and I thought, wow, he has -- he supports my opinion, and that's the reference.

Q. If you cannot rely on the testimony of Dr. Xue, a native Chinese speaker, do you feel that you have sufficient evidence in the record aside from Dr. Xue to support your opinions?

A. Yes.

THE COURT: Can you ask that question again?

MS. BROWN: Sure.

BY MS. BROWN:

Q. I want you to assume you can't rely on Dr. Xue's opinion as a native Chinese speaker and as an organic chemist about this email, okay.

Does that change or affect your ability to opine or evaluate plaintiffs' experts' opinion about this email?

A. No. I have spoken to Jucai Ge who said, no, it's not about that.

Q. Okay. And finally, Dr. Afnan, we started with a review of your sort of overall key opinion, the plaintiffs' experts' opinions that ZHP violated cGMP are not supported by the regulatory record.

We are here today because plaintiffs have filed a motion saying all of your opinions are based on Dr. Xue.

Is that the case?

A. No. None of my opinions are based on Dr. Xue.

Q. All right.

MS. BROWN: Thank you very much, Your Honor. I have no further questions.

THE COURT: I have a question for you.

MS. BROWN: Yes.

THE COURT: Are you also seeking a ruling on the paragraphs that Judge Kugler had precluded?

MS. BROWN: And, Your Honor --

THE COURT: Or has that already been ruled on or is that withdrawn, or tell me?

MS. BROWN: I understand, Your Honor, based on the motion in limine arguments and the Court's rulings that it perhaps has already been resolved.

As I understand that motion, Judge Kugler had allowed plaintiffs' experts to say that these products were adulterated the entire time.

I understand what is not permitted is for anyone, including Dr. Afnan, to say, as a matter of law, adulteration cannot be applied retroactively, right? That's a legal opinion. That is not excluded.

But what I understood, and please correct me if I'm wrong, is that just as plaintiffs' experts can say it was adulterated all along based on my regulatory opinion, Dr. Afnan can similarly say it was not adulterated and there was no cGMP violation in the past, prior to 2018.

THE COURT: And that is -- I mean, I believe that that's how it should be. But I wasn't clear whether or not I had given you a ruling on your motion to, I think, amend the Order.

MS. BROWN: We had not officially, Your Honor. As I read the July transcript --

THE COURT: Okay.

MS. BROWN: -- it was deferred to this hearing. I thought there were other statements that may have resolved it. But that would be our view of the state of affairs as it relates to that testimony.

THE COURT: Well, so what are you saying to me? You need a ruling or you don't need a ruling?

MS. BROWN: Well, yes, I think probably we should be clear. If the Court would confirm, as I understand it, that plaintiffs' experts can say, based on a regulatory, not a legal opinion, that they believe it was adulterated all along and Dr. Afnan, pursuant to the Court's approval, could say, based on a review of the regulatory record, it was not adulterated until the FDA said it was in November of 2018, I think that resolves the issue of the inconsistencies that was briefed that led to this cross-motion.

MR. SLATER: Your Honor, I don't think that resolves it. I think it's a quick way to try to get around the fact that his opinion was barred, because what Dr. Afnan did was very different from what the plaintiffs' experts did. They're not in the same -- they have different credentials. They have different qualifications and backgrounds. They didn't take the opinion, which if you boil it down as well, you can't say it was adulterated retrospectively, which was a legal conclusion, which was properly barred by the Court.

And I don't think that this argument can suddenly

cure that because that's what Dr. Afnan's opinion was. He made a legal conclusion that you can't say it was adulterated until the FDA says it's adulterated. And that was a legal conclusion that was barred. And it's also inconsistent with Your Honor's ruling, which is that nobody can say that. The jury will decide from day one, based on the evidence and the opinions they hear, whether it was adulterated, based on the facts and the regulatory standard for what adulteration is. That's where we were when we walked in. And nothing has happened in this courtroom to change that.

And my sense is that what counsel has done -- I have a whole cross on adulteration because I thought there was going to be time spent on this to try to --

THE COURT: Well, that's why I'm asking the question.

MR. SLATER: Yeah.

THE COURT: Because I understood the motion to be that -- I hadn't -- I didn't think I had ruled on it -- that Judge Kugler was -- you know, he employed one standard for the plaintiffs and one standard for the defendants. And so I may have called it a goose/gander, which I like to call. And I don't recall that I had ruled on it, which is why I was asking counsel.

MR. SLATER: No.

THE COURT: But when I read through the brief, it did seem -- when I read through the defendants' brief, it did seem

that Dr. Afnan should not have been precluded in some of these areas. And so if you folks haven't worked it out, then we'll just -- we'll plod through it.

MR. SLATER: Yeah. I mean, I assumed that he was going to go through. When there was no testimony, I thought they were withdrawing that opinion from him so I wasn't going to cross. I was going to ask for a few minutes to move these notes off the table. But, I mean, I have --

THE COURT: Well, I'm looking at the motion, there's only, let's see, six -- let's see.

Well, I guess I'll start by saying I'm looking at Judge Kugler's Order. So it's one, two, three, four, five, six -- six paragraphs I think that are at issue, at least.

MR. SLATER: Right.

THE COURT: I don't have the docket number of the defendants' motion, but Judge Kugler's order was 2581. Docket 2581. And I thought that's what was being challenged.

MR. SLATER: Your Honor actually clarified, and counsel told us at one of the prior hearings when you started to look at this and then declared we have a *Daubert* hearing that they withdrew their motion as to three of the paragraphs.

THE COURT: Okay.

MR. SLATER: And they were only pursuing it as to two of the paragraphs, which are 24 and 138.

THE COURT: Yeah.

MR. SLATER: Which are identical. It's exactly the same language. It's just in two places. And then there was another paragraph which had been barred, which was an opinion that the drugs continue to be therapeutically equivalent, which I don't really understand what that -- the import of that is or what that would mean at the present time. I don't really understand that.

THE COURT: The relevance of it?

MR. SLATER: I'm sorry?

THE COURT: The relevance.

MR. SLATER: Yeah. I don't see any relevance to it. I don't see how that fits the case. They're not selling NDMA tainted. They're not even selling valsartan in the United States anymore at ZHP. So that shouldn't be in.

So if they want to try to put him up on adulteration, his opinion has like five different parts to it, and I'm ready to go through every single part of it and take it apart piece by piece, because the legs are going to fall apart as I go. So I don't know if they really want to pursue this. But I certainly don't want to concede that just through a quick argument he can suddenly give that opinion.

THE COURT: Well, I don't know that you need to pick it apart. That sounds like you're attacking -- that sounds like a weight of the evidence kind of --

MR. SLATER: I mean from a methodology and the

standpoint of whether or not he can actually say the things that he wants to say. Because he relies on things like, for example, Valisure, who filed a citizen petition, said, well, we think that we found NDMA in Diovan. And he relies on that for the opinion to say, well, how can it be adulterated if Diovan has it. So there's a whole cross on that, including the fact that he never investigated the reliability of those results. No one ever did a *Daubert*. No one deposed anybody. The FDA found very significant analytical violations to cGMPs in the testing that was used for this.

And Diovan was tested by Health Canada, and it was found not to have NDMA, as the FDA confirmed. I mean, I can go on and on. That's just one of the bases.

THE COURT: All right.

MS. BROWN: May I be heard, Your Honor?

THE COURT: Yes.

MS. BROWN: Thank you.

So I think there's two separate issues here. And here's where I think it has been resolved. No one, neither side, can opine as to what adulteration means as a matter of law, as a legal matter, right? We understand that that's off limits for their experts and our experts.

THE COURT: True.

MS. BROWN: What I believe is the goose/gander argument is if, from a regulatory perspective, their experts

are going to be able to say I looked at the regulatory record, my interpretation of the warning letter and the documents says that this was adulterated during the entire time period, then Dr. Afnan, who is actually the only expert who worked in CDER, should be allowed to say absolutely not, I disagree. Based on my expert review of the regulatory record, not as a legal matter, I believe they were not adulterated until the FDA made that determination in November of 2018.

So the goose/gander issue is just not as a matter of law, but as a matter of an interpretation of the regulatory record, both sides' experts either have no opinion on this or should be allowed to offer conflicting opinions.

MR. SLATER: The problem being, the experts are not the same. Dr. Afnan is countering Dr. Najafi, who also is a chemist and qualified as a chemist in this case, which Dr. Afnan, as I'm going to get to, is not put forward as a chemist. And when I tried to ask questions in his deposition, I was blocked and they said beyond the scope of his expertise.

And Dr. Plunkett also is a toxicologist. They have different backgrounds. They have very different methodologies, because they were reasoning, in addition to certain other things, they used the statutory definition of adulteration, which Judge Kugler said with Dr. Najafi in particular, he needs to stay within that definition and talk about how that definition is met or not. That was a very important part.

And the analysis of what they did is very different. They actually also used the FDA finding of adulteration whereas Dr. Afnan is saying, well, the FDA is -- you can't apply it as a legal matter. And that is a legal conclusion. So they're not -- the defense used the word "goose/gander," but it's not apples to apples. It's very different. And that's why Judge Kugler treated the experts differently, as they should have been.

So if they want to pursue this, I'm ready to cross Dr. Afnan on this if they really want to and lay it out, and I'm fine doing it.

THE COURT: Okay.

MR. SLATER: I'm happy to do it. I'm ready to go. I just thought they were -- I don't agree that somehow everyone has to be treated the same because they're not the same.

MS. BROWN: It seems like a --

THE COURT: Well --

MS. BROWN: I apologize, Your Honor.

THE COURT: Go ahead.

MS. BROWN: It just seems like a very easy issue, Your Honor. We are not talking about as a legal matter. We are talking about competing regulatory experts.

And counsel suggests somehow Dr. Afnan is not qualified. His experts never worked in CDER. They don't have the FDA experience. They are --

THE COURT: Well, I don't have a handle on who is who.

MS. BROWN: Understood.

THE COURT: But if you have a regulatory witness who is similarly situated as this witness and your witness can say that they were adulterated, it seems to me that given his expertise, which parallels your witness's expertise, he can say the opposite if his basis says it.

MR. SLATER: That's not the case. I'm sorry, Judge.

THE COURT: But you're telling me that your experts are toxicologists and not regulatory experts.

MR. SLATER: One is a toxicologist and a regulatory expert, Dr. Plunkett. One is a chemist and has regulatory background, and cGMP background. The matchup to Dr. Afnan was our expert, Dr. Bain, who got eviscerated on *Daubert*. And I think that if I wanted to start making goose/gander arguments, I would start doing that. But I don't think that's a legitimate argument.

THE COURT: Who's the regulatory expert that is similarly situated as this witness, your expert?

MR. SLATER: It was Dr. Bain, who got cut back very significantly. That's the matchup with Dr. Afnan, because he told us, he's here to give opinions on cGMPs. That's what he said his expertise was. That's what he said he was put forward for. Now he wants to give the opinion, well, I worked at the

FDA so I can sweep aside an FDA finding and not grapple with it and say, well, looking back, it's not legitimate to call it "adulterated." That's his opinion. That's the sum and substance of his opinion, which is a legal conclusion.

THE COURT: Who are Najafi and Plunkett? Are they toxicologists?

MR. SLATER: Najafi is the chemist and regulatory expert, also has cGMP experience. He actually runs a lab. Dr. Plunkett is a toxicologist and a regulatory expert.

THE COURT: I can -- I won't quarrel with your argument with respect to Plunkett, but I would seem to have a quarrel with Najafi.

MR. SLATER: If he --

THE COURT: Because I don't see a distinction between that witness and this witness.

MR. SLATER: In Judge Kugler's decision, what he said was he's going to let Najafi say it, but he has to adhere -- and I'm paraphrasing -- to the language of the statute.

Dr. Afnan's opinion is not -- Doctor, right?

(Witness nodding.)

MR. SLATER: Dr. Afnan's opinion is not grounded in the definition of adulteration. It's grounded in, well, you can't call it adulterated retrospectively. And that is absolutely a legal conclusion which Your Honor has already precluded on the MILs. They're not -- even though counsel is

saying, well, they're similar so you should let them all do the same thing, their methodologies were different, how they approached it were different. They're not the same. Even if they had exactly the same credentials, if they had a different methodology, he's disagreeing with an FDA finding. He has a different uphill climb, and he's trying to do it by saying, well, I just can tell you, you can't say it was adulterated from day one.

He has no basis for that. He has nothing he's looking at other than that's just my opinion. It is a legal conclusion that Your Honor's already precluded any witness from giving in this case on the MILs. You said that you can't say that a retrospective analysis can't be done and you can't say in retrospect it was adulterated. That's already been precluded from anybody saying it. So he's now trying to say what Your Honor has already barred anybody from saying.

MS. BROWN: That's not true at all, Your Honor. This is very -- what the Court has barred is somebody saying that this adulteration finding cannot legally be applied retroactively. Nobody should be doing that. It's a legal opinion. It is not coming into the case. We understand that.

What counsel is proposing is taking multiple experts and having them, under the guise of regulatory expertise, opine on their expert view of the regulatory history, the regulatory documents, the regulatory experience, if they have any, what

that means for when these drugs became adulterated. That is a regulatory opinion. That is untethered to a legal opinion. It stands alone. And if permitted to come in through Najafi and Hecht and Laura Plunkett, none of whom ever worked and stepped foot in the FDA, then certainly Dr. Afnan who has firsthand experience --

THE COURT: If the plaintiffs' witnesses are testifying in their regulatory capacity and they, given their regulatory expertise, opine that these drugs were adulterated before the FDA declared them adulterated, this witness will be permitted, given his expertise, to counter that. That's my ruling.

MS. BROWN: Thank you, Your Honor.

MR. SLATER: Will I have an opportunity to cross him on this though as part of the hearing so Your Honor can hear what the bases for his opinion are and see if they fall away?

THE COURT: Are you challenging the bases of his opinion?

MR. SLATER: Oh, yes.

THE COURT: Then go ahead.

MR. SLATER: I think that his methodology, and I gave you the example of relying on Valisure, I don't think that he should be allowed to talk about Valisure.

THE COURT: Then go ahead. Go ahead. That's a 702 issue.

MR. SLATER: Yes.

THE COURT: But generally speaking, I would permit it, assuming I find that it meets the 702 gatekeeping mission.

So I won't go through the paragraphs that the defendants have asked me to reconsider that Judge Kugler precluded. You understand the general parameters of my ruling.

MS. BROWN: I do. Absolutely. Thank you, Your Honor.

THE COURT: Okay.

MR. SLATER: My only question before I cross him, Your Honor, so I don't want to do it if you don't want me, I assume he cannot say it wasn't adulterated because you can't retrospectively say it was adulterated. Because Your Honor already ruled on that. I assume he can't give that information.

THE COURT: As a matter of law, that's right.

MR. SLATER: Okay.

THE COURT: In his regulatory experience, he can.

MR. SLATER: Okay.

MS. BROWN: Thank you, Your Honor.

MR. SLATER: And I'll question him on whether his methodology is credible to give that opinion.

THE COURT: Right. Let's take a five-minute break.

MR. SLATER: Thank you.

MS. BROWN: Thanks.

THE COURTROOM DEPUTY: All rise.

(Recess was taken from 2:58 p.m. until 3:07 p.m.)

THE COURTROOM DEPUTY: All rise.

THE COURT: Please resume the stand, please. Thank you.

MR. SLATER: Your Honor, if you don't mind I cross from counsel table, is that acceptable to the Court?

THE COURT: Yes. Can you just keep your voice up?

MR. SLATER: I will.

THE COURT: I am hard of hearing.

Okay. You can have a seat. Thank you, all.

(Witness whispering to the Court.)

THE COURT: Pardon me?

No worries.

MR. SLATER: If I sound like I'm yelling, please give me a --

THE COURT: You sound like you're yelling.

(Laughter.)

THE COURT: You're always yelling at me, Mr. Slater.

MS. BROWN: All the time.

MR. SLATER: Never. Never.

(Laughter.)

THE COURT: Okay.

Go ahead.

MR. SLATER: Thank you.

CROSS-EXAMINATION

BY MR. SLATER:

Q. Good afternoon, Dr. Afnan.

A. Good afternoon.

Q. I just want to see if we can agree on a couple basic things. In your report on page 4, paragraph 16, you said that your role here was to respond to four of the plaintiff experts, right?

A. Yes.

Q. Regarding ZHP's compliance with FDA requirements, including cGMPs, in connection with the manufacture of the valsartan API. That was the scope of what you were retained for in this case, correct?

A. Yes.

Q. One thing you did not do is you did not evaluate the manufacture of the finished dose by ZHP at the -- I think it's pronounced Xunqiao plant. You did not look at that at all. It was not something you considered, correct?

A. It was not in the scope of my assignment.

Q. So you only looked at the manufacture of the API, correct?

A. Correct.

Q. Okay. Now, I think you mentioned earlier that you are not a synthetic organic chemist.

A. Correct.

Q. Dr. Xue is, correct?

A. Correct.
Q. And you told me when we met previously that your role was to look at the plaintiffs' GMP experts and assess only GMP issues, correct?
A. Can you refer me to that? My role was --
Q. Well, let me ask you the question now.
Am I correct that your role was to look at the plaintiff GMP experts and assess GMP issues? Can we agree with that basic proposition, which I thought you agreed with a moment ago?
A. My role was to read the reports and respond to those reports and specifically four of the experts.
Q. Can you look at your deposition, page 170, line 23, please?
MR. SLATER: Your Honor, I handed a transcript up to you --
THE COURT: Yes. Thank you.
MR. SLATER: -- earlier.
THE WITNESS: Page 170.
Page 170, line 23.
THE COURT: Twenty-three.
BY MR. SLATER:
Q. Line 23. I just want to go right to your answer where you said: "My role, my remit, was to look at the plaintiff experts and assess GMP -- GMP statements. I was not here on this

project to assess the chemistry. For that, there was Professor Xue."

That is correct, right?

A. That is what I said there. I was not to look at chemistry, but I was to look at everything that had been submitted by your experts, yes.

Q. Okay. I -- I'm surprised we're going to go back and forth on this.

A. Okay.

Q. But I want to be very clear. You said --

THE COURT: I think you're saying the same thing. He responded to the experts' reports.

THE WITNESS: Yeah.

THE COURT: But with respect to the chemistry part of it, he did not.

THE WITNESS: Correct.

BY MR. SLATER:

Q. And for the chemistry part, what you told me under oath in the deposition was that for that, Dr. Xue addressed the chemistry, correct?

A. Correct.

THE WITNESS: Thank you, Your Honor.

BY MR. SLATER:

Q. And I want to go through a couple of examples, because there were things that you talked about that I just want to

make sure we're on the same page and the Court understands how you drew that line in drawing your opinions, okay?

A. Okay.

Q. For example, when I asked you during the deposition how did the NDMA form, the chemical reactions that occurred, do you recall that your counsel or the counsel that retained you objected and said that was outside the scope of your opinions?

A. I do not remember.

Q. You --

A. But if you say it did, then it did.

Q. You'll agree with me that a simple question of how did the NDMA form is beyond the scope of your opinions, as your counsel said at the deposition? You do agree with that, right?

A. So as a chemist, that's beyond the scope. As a regulatory expert looking at exchanges with the Food and Drug Administration, it is not beyond the scope. So if I look at it and say what was the cause of formation of NDMA, yes, it was a process change.

Q. Okay. In terms of what actually led to the NDMA forming, you understand you may know things outside of this courtroom, but you were put forward as an expert for a specific purpose. You agree from a chemistry perspective, you don't know how that happened. That's what you told me in the deposition, right?

A. I do not know. However, again, if I look at --

Q. I'm sorry.

A. Okay.

MR. SLATER: I was just going to ask, Your Honor, if I could get just a direct answer if I ask a direct question.

THE WITNESS: Okay.

THE COURT: I think we're quarreling over something we don't need to quarrel.

He's explaining on what bases he's testifying. He is not a chemist, and he's not going to testify as to, you know, how the chemicals formed NDMA.

BY MR. SLATER:

Q. And I'll give another -- and I want to ask you another question. When I asked you if you evaluated the temperatures reached in the zinc chloride process and their impact on the dimethylformamide, the DMF, you said, "Again, my remit here was not chemistry."

So, again, another aspect of the chemistry that was significant to how this occurred, you said that's not what you looked at. And, again, that's what Dr. Xue covered, correct?

A. Correct.

MS. BROWN: And, Your Honor, if it's helpful, we're not putting him up on the specific chemistry --

THE COURT: Well, I think that's why I said we are unnecessarily quarreling over something we don't need to quarrel about.

MS. BROWN: Thank you.

MR. SLATER: And this will now go, I think, a little bit more into -- it starts to transition us to the knowledge issue, which I think is an important issue here that we did hear some opinions on.

THE COURT: Okay. Hopefully.

BY MR. SLATER:

Q. You have no opinion whether ZHP should have been aware of the potential for dimethylamine to be an impurity of the DMF it used in the zinc chloride process. You have no opinion on that question, right?

A. I have regulatory opinion, not chemistry opinion.

Q. Well, let's go to page 201, please.

A. 201. Yes.

Q. I asked you on page 201, line 15: "Doctor, do you, yes or no, have an opinion -- I just want to know if you have an opinion. I don't want to know what it is -- as to whether or not ZHP should have been aware of the potential for dimethylamine to be an impurity of the DMF it was using in the zinc chloride process? Yes or no? Do you have an opinion?"

And if we flip to the next page, on page 202, line 3, you said: "I can't answer that. I genuinely can't [sic] answer that," correct?

A. Yes; because I'm a regulatory --

Q. Is that what your answer was, sir?

A. Yes. It's on the page.

Q. Okay. And you would agree with me that the dimethylamine -- well, maybe you don't know. The dimethylamine was an impurity and/or a degradation product of the DMF and that then combined with the nitrous acid during the quenching phase to cause the NDMA to form, do you know that now as you sit here or do you not even know that?

A. Now that I sit here, where it's all public domain, I have some awareness of it. But I'm not here as an organic chemist. I'm here as a regulatory expert.

Q. Now, you said that you didn't rely on Dr. Xue at all to form any of the opinions, and you just happened to see his report the night before you signed your report. Is that -- did I hear you correctly?

A. (No response.)

Q. Is that what you said on direct, that you wrote your entire report, formed all of your opinions --

A. Yes.

Q. -- independent of ever knowing what Dr. Xue's opinion was?

A. I --

Q. And then the night before you wrote your report or signed your report, I should say, you happened to see his report and then that was it?

A. That's what I have sworn to have done, sir.

Q. Okay. Just want to make sure I understand it.

A. Okay.

Q. Let's look at paragraph -- you have your report in front of you, right?
A. I do.
Q. Let's look at paragraph 141, which is on page 55.
A. Yeah.
Q. Now, I'm not going to read the entire paragraph, but I'm going to paraphrase it as I go. And if I skip something or do something that's not accurate, you can stop me and say, hey, you missed something important.
A. Uh-huh.
Q. You said, "As an initial matter, the FDA and ICH regulations and guidance in place prior to the discovery of NDMA in valsartan API in May 2018 did not require ZHP to test its products for NDMA or NDEA specifically."

You then go through some other language, and then ultimately you say: "As explained in detail, in the report of Dr. Xue, ZHP's scientists did not have a reasonable scientific basis to expect that NDMA or NDEA could form during either the TEA with quenching or zinc chloride processes; thus, ZHP did not have a reason to investigate nitrosamines at the time the company was performing its risk assessments for these processes." And you cited Dr. Xue's report, correct?
A. Yes.
Q. And you, again, since you're not holding yourself out as an expert in chemistry, you had no opinion and you don't have

the ability to form an opinion as to what a scientist reasonably should or shouldn't have known as to whether or not they should have thought of the possibility of nitrosamine formation and evaluated that as part of the risk assessment? You have no opinion on that subject --

A. I do.

Q. -- because you're not a chemistry expert in this case, right?

A. I do, sir. I do.

If I can go back to 141 and read the rest of the section that you missed out. "As an initial matter, the FDA and ICH regulations and guidance in place prior to the discovery of NDMA in valsartan API in May 2018 did not require ZHP to test its products for NDMA or NDEA specifically. Instead, as described in Section IV above, relevant guidance and regulations relevant to cGMP for API manufacturers required investigation of impurities that were reasonably expected to occur in the manufacture of a drug substance."

"Indeed, the FDA has expressly stated that it generally needs to be recognized that there is a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for."

Do I ignore that and just stick to the sentence about Dr. Xue?

Q. Well, what you just read is the regulatory standard which

is just the general standard.

In terms of how to apply that standard as a matter of methodology, you had to rely on Dr. Xue's opinions as to whether or not that risk should have been recognized and evaluated as part of the risk assessment. That's what you said right there in your report, that you relied on Dr. Xue for that point?

A. For that point.

However, my conclusion of did ZHP test for valsartan, NDMA in valsartan, no. Did they do any testing to identify impurities? Yes. Did they adhere to regulations? Yes.

Q. Well, let's come back to this. I really just want to make sure that we can just get a clean record on this one question.

Your methodology, if I understand it, for cGMP is there are certain regulatory guidances that are binding and needed to be followed by ZHP here, right?

A. Yes.

Q. And if those were violated, they violated cGMPs, right?

A. Yes.

Q. And you just told us a little while ago you actually agree with the FDA that ZHP violated cGMPs in the risk assessment and manufacture of the valsartan as described in the warning letter. You just told the counsel that retained you that you don't disagree with the FDA findings in the warning letter. Did I hear that correctly?

A. I think you heard that. I didn't qualify it by saying in terms of risk assessment.

What that --

Q. Sir, I just want to know if that's what you said and that was your opinion. It's really -- it will go much quicker if we can go with my questions instead of -- and I promise you, your counsel can ask you follow-up. But you conceded --

MS. BROWN: I'm sorry, Your Honor, could he just be permitted to finish his answer?

THE COURT: So here's what I'm going to say --

MR. SLATER: Okay.

THE COURT: -- if you want your witness to answer with a yes or no, you will tell your witness to please answer with a yes or no, to which I will say to your witness, or a witness: If you can't answer with a yes or no, you'll tell counsel that you can't answer it with a yes or no, and you will be permitted to explain it. Okay?

THE WITNESS: Thank you.

MS. BROWN: Thank you.

THE COURT: So we understand the ground rules.

MR. SLATER: I do, Your Honor.

MS. BROWN: Thank you, Your Honor.

THE COURT: Ask your question.

BY MR. SLATER:

Q. Yes or no, you just conceded, when counsel for ZHP was

questioning you, that you don't disagree with the FDA findings of GMP violations as set out in the warning letter? That's what you told us on the direct exam, correct?

A. Yes.

Q. And the warning letter has various violations. And one of them included that the risk assessment was a deviant risk assessment because it didn't comply with good manufacturing practices. That was not an artful question. Let me ask it again.

One of the findings by the FDA was that ZHP failed to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API, and that would be the risk assessment, correct?

A. That's what is in the warning letter, yes.

Q. And you don't disagree with it as you just told us, right?

A. Correct.

Q. Okay. And let's just, as we start to jump ahead now into certain other areas, that risk assessment they're talking about occurred before one pill got sold in the United States. The risk assessment happened at the very start before they even started selling the API to be put into finished dose and sold in this country, right?

A. I don't have that evidence. Perhaps you can show me that.

Q. Are you telling this Court you don't know when the risk assessment was performed?

A. The risk assessment was performed. You did not ask me if a risk assessment was performed. You said that risk assessment that did not find NDMA was done and completed before one pill was sold.

Q. The risk assessment that the FDA is talking about in the warning letter is the risk assessment that was done on the manufacturing process for ZHP to then say, okay, we can check all the boxes and we can start selling this stuff. That's the risk assessment the FDA is talking about, correct?

A. That there was a risk assessment.

Q. Am I correct, yes or no, that that's the risk assessment before they ever started manufacturing for commercial sale?

A. They were in commercial sale when they changed the process. The risk assessment that was performed, which took over nine months, is there. The challenge that FDA gave them through the observation was that they had not looked at formation of NDMAs. The lacking in the risk assessment is because ZHP did not test for NDMA. You need to read the 483 observations to see that.

Q. Okay. Let's just --

THE COURT: The question is, the risk assessment that's referred to in the warning letter, when was that risk assessment to have been done?

THE WITNESS: That was done, Your Honor, when the change -- or before the change was implemented.

BY MR. SLATER:

Q. And, again, before the change could be implemented, a cGMP compliant risk assessment had to be performed, correct? That's what the law says, right?

Before you can implement a change to a manufacturing process, you have to evaluate it with a risk assessment and a change control process that complies with cGMPs, correct?

A. In a roundabout way, yes.

Q. And if that risk assessment and that change control process deviates from GMPs, as you've agreed on the stand occurred, every pill that would be sold after that GMP deviant analysis was done would technically be adulterated under the definition under the United States Code, correct? Under the words of the Code, it would be adulterated, correct?

A. I can't give a yes-or-no answer.

Q. Why not?

A. Because it's not as simple as yes or no.

Q. Okay. Well --

THE WITNESS: Can I explain, Your Honor?

THE COURT: Could you, please.

THE WITNESS: Yes.

So the risk assessment was done. Your statement, your premise was that if the risk assessment is not compliant to cGMPs, there is no written rules of how to do a risk assessment to be compliant with cGMPs. The requirement is to

do a risk assessment to see whether impurities would form. ZHP did that. Was it good enough, based on the warning letter date of November 2018? And the investigator in June 2018 said, no, you could have done better. But there isn't a black and white your risk assessment is compliant or your risk assessment is not compliant.

BY MR. SLATER:

Q. Well, in this case ZHP did a risk assessment, right?

A. Yes.

Q. And the FDA looked at that risk assessment and said it did not meet cGMPs. That's what the warning letter found, right? That is the conclusion, isn't it? Here, let me do this.

A. Can I get --

Q. So we don't have to talk -- I'm going to --

MR. SLATER: Your Honor, can I approach and hand the warning letter to the witness and to Your Honor, if you would like it?

THE COURT: Okay.

MR. SLATER: Thank you.

THE COURT: I think he has it in his binder.

MR. SLATER: Do you have the warning letter with you?

THE WITNESS: I don't think so.

THE COURT: Isn't it in here? Maybe it's hard to read.

THE WITNESS: No. It's --

MR. SLATER: I think it's just like a snapshot of --
THE WITNESS: It's the first page.
THE COURT: Okay.
MR. SLATER: Your Honor, may I?
THE COURT: Okay.
MR. SLATER: Thank you.
THE WITNESS: Where is it, Mr. Slater?
MR. SLATER: I'm getting to it. But I got papers stuck. Here you go.
MS. BROWN: Thank you.
MR. SLATER: You're welcome.
BY MR. SLATER:
Q. So let's look where we were just talking at the fourth page of this warning letter.
A. Yeah.
Q. And it's Deviation No. 2 titled: "Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API."
Do you see that?
A. Yes.
Q. And let's go through it. I think it's important to go through, isn't it?
A. Yes.
Q. I mean, this is what you're here for, cGMP.
A. Yes.

Q. And these are admitted violations now, right?

THE COURT: Does this go to 702, your 702 challenge?

MR. SLATER: Absolutely, Your Honor.

THE COURT: All right.

MR. SLATER: Because if the witness is going to say that the drugs were not adulterated, if they violated cGMPs in the manufacture, by definition under the statute they were adulterated.

MS. BROWN: But, Your Honor --

MR. SLATER: And I think his methodology would be faulty because he's essentially drawing a conclusion that is contrary to what the law is. And I think Your Honor, as a methodological matter, can say I'm not letting a witness give an opinion that's not consistent with the law.

MS. BROWN: And, Your Honor, but that's his legal interpretation of this legal regulation. And that's not the opinion he's being offered for pursuant to the Court's rulings.

THE COURT: Okay. I -- I see. But let me hear it so I can be better informed, and you can make your record.

Okay. Go ahead.

BY MR. SLATER:

Q. So let's look at what the FDA said, because I think this is going to be important for the whole questioning that I'm going to do with you today.

A. Yeah.

Q. They start out, "in November 2011" -- so now that orients us on when this occurred, right?

-- "you approved a valsartan API process change," and it gives the number of it, right? That's how those things are coded, right?

A. Yes.

Q. "That included the use of the solvent DMF. Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process."

Now, I'm going to stop there. When they talk about "failing to adequately assess the potential formation of mutagenic impurities," they're talking about what you said that Dr. Xue had given an opinion on, that you relied on that, well, they didn't need to know about it, and therefore, there's nothing -- nothing was done wrong, no harm because it wasn't reasonably knowable. But the FDA actually thought they should have more adequately addressed it. That's what we're talking about, right?

A. 2018 -- 2019 FDA Commissioner also stated that nobody knew about the formation of NDMAs.

Q. We're going to get to those statements, okay.

A. Okay.

Q. I'm looking forward to asking you about that. I know you

want to talk about it. There's language we haven't talked about yet in those statements, right?

A. I don't know --

Q. There's some language we didn't talk about in there, right?

A. I don't know what you wish to bring up.

Q. Okay. Well, we'll get to it.

And then it says -- this is the FDA describing a GMP violation you agree occurred in 2011.

"Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant, dimethylamine."

Do you see that?

A. Yes.

Q. So the FDA said to ZHP back in 2011-2012, you failed to adequately assess these risks in your process. That's what this is saying, right?

A. In 2018, with --

Q. Is that what this says?

A. In 2018, with hindsight, FDA is making a statement after FDA knows that this is the process and this is the cause of formation of NDMAs. FDA had been on site. FDA had seen what's going on. FDA was not asleep. FDA was doing its job. Formation of NDMAs from DMF was not generally known.

Q. When the FDA thinks that a manufacturer did everything it could and complied with all the cGMPs but just happened to just run into a situation nobody could have ever known, they don't give a warning letter to them. They don't punish them with an import ban and preclude them from selling drugs into the United States for four years. Do they do that when they don't think someone did anything wrong? Is that what happens? Because you worked there for a long time. Is that what the FDA does?

A. Can you rephrase your question, please?

Q. Sure.

A. It's multiple statements.

Q. You're saying to us basically, well, they're looking back at hindsight and, you know, no harm, no foul, and it's just, you know, whatever, it didn't really mean anything. But the FDA wouldn't send an official warning letter finding cGMP violations and imposing an import ban, as they talk about a few pages later, precluding the company from selling drugs into the United States if they didn't think it was significant, would they?

A. So --

Q. Yes or no, would they?

A. I can't give a yes-or-no answer.

Q. Fine.

A. Because --

Q. You can't answer that with a yes or no.

And that, based on your methodology and your understanding of the facts and the law and the regulatory guidances that control, you're not able to answer that question with a yes or no; am I correct? Yes or no?

A. Can I explain?

THE COURT: Yeah. Would you, please.

THE WITNESS: So the reason I can't answer is because you put multiple questions which are related, but actually the desire is for me to say yes. It's not going to work with me.

So the issue that I see here is that FDA is telling ZHP you did not look at NDMA formation because of DMF. DMF is a very common solvent which has been used by industry throughout, and that was an unknown. Again, going back to regulations which says reasonable expectation of formation of mutagenic impurities. That's not there. That was not there at that time.

Now, we come to the import alert. Import alert which was implemented on ZHP at that time.

THE COURT: What are you saying? You come to what? What are you saying?

THE WITNESS: Oh, the import, import alert.

THE COURT: Okay.

THE WITNESS: The import alert specifically was there to prevent drug product manufacturers bringing product in. At the time of the warning letter and the import alert, there was

no drug product in the market. There was no API in the market. The API was not being marketed. So effectively the import alert is well post event.

BY MR. SLATER:

Q. The import alert, if you want to go two pages later, was imposed on September 28, 2018, right?

A. Yes.

Q. Okay. So let's go back to my question.

Would the FDA serve a warning letter on ZHP and say you violated cGMPs if the FDA didn't think that they actually did violate cGMPs?

A. No.

Q. And would the FDA --

THE COURT: This question has been -- it's maybe more curiosity, does the FDA -- you worked at the FDA.

THE WITNESS: Yes.

THE COURT: Does the FDA ever take responsibility for its own falling down on the job?

THE WITNESS: So I think the press releases where FDA says we didn't know and they didn't know is there. FDA does go back to industry and say that was an issue that needs to be resolved and let's resolve it together. FDA does have those conversations with industry. They're not public about it, but they do go to industry.

THE COURT: And so similar question, when they issue

warning letters, do they ever do a mea culpa or --

THE WITNESS: No.

THE COURT: -- they always blame the manufacturer?

THE WITNESS: It's the manufacturer. In fact, there are many firms with warning letters whose products are currently today on the market and the warning letters stand.

THE COURT: Okay.

BY MR. SLATER:

Q. You're not sitting on this witness stand and saying that the NDMA contamination is the FDA's fault?

A. No.

Q. That's not your opinion, right?

A. No.

THE COURT: That's not what I asked him.

MR. SLATER: I understand. I'm just trying to take it to the next step.

BY MR. SLATER:

Q. And, in fact, you agree that ZHP was responsible for the quality and purity of the valsartan API at manufacture, correct?

A. According to current good manufacturing practices and according to the rules and regulations current at the time of manufacture and release, yes. ZHP was responsible and acted accordingly.

Q. Was ZHP responsible for the quality of its drugs?

A. I said yes.
Q. Okay. The FDA wasn't responsible for the quality of the drugs that were being manufactured by ZHP. It was ZHP's responsibility, right?
THE COURT: He said "yes."
THE WITNESS: I did say "yes."
MR. SLATER: Okay. Good.
BY MR. SLATER:
Q. Now -- and you know what, I'm going to give you something a little bit out of my -- out of order here.
MR. SLATER: If I could, Your Honor, I have the January -- I know I have it here. The January 25, 2019 FDA statement that Dr. Afnan has referenced a few times. May I hand it?
THE COURT: Okay.
THE WITNESS: Thank you.
MR. SLATER: You're welcome.
(Handing out documents.)
BY MR. SLATER:
Q. Okay. So this is one of the FDA's statements that you talked about quite a bit earlier today, right?
A. Yes.
Q. And let's look at page 2. And I'm sorry for the weird stapling and the sideways thing. I don't know how that happened, but it wasn't meant to throw you off.

So if you go down to the fourth full paragraph, let's look at what it says.

"We've placed a ZHP facility on import alert to stop all its API and finished drugs made using ZHP's API from legally entering the United States."

Do you see that?

A. Wait. In --

Q. The fourth paragraph.

A. The fourth paragraph which begins with "we've also worked"?

Q. It starts with the words "since then."

A. Page 2?

Q. It's the second page. I'm sorry.

THE COURT: Yes.

BY MR. SLATER:

Q. Do you see that? It's the second page.

A. Oh, fourth paragraph. Yes. Sorry. I was looking at the fifth.

Q. Sure. And I'll start from the beginning.

A. Yeah.

Q. It says, "since then," this is now since the summer of 2018.

A. Yeah.

Q. "The FDA and additional manufacturers of other ARB medicines have identified more cases of NDMA impurities, as

well as NDEA impurities."

You with me?

A. Yes.

Q. Now I'm going to go through the part I wanted to read with you. "We've placed a ZHP facility," and that's the Chuannan facility, correct?

A. Yes.

Q. "On import alert to stop all its API and finished drugs made using ZHP's API from legally entering the United States. We also issued them a warning letter outlining several manufacturing violations, including impurity control, change control, and cross-contamination from one manufacturing process line to another. It's unlikely" -- well, let me stop there for a second.

So that's one we didn't hear about on the direct that actually ZHP also identified that not only was its risk assessment faulty and not only didn't they realize there was a chance for these nitrosamines to form just from the manufacturing process, but they also found out -- and it's in their deviation investigation report -- that they weren't cleaning their production lines adequately. So when they were running one set, one batch together, it was getting contaminated with the nitrosamines from the prior batch, right? They figured that out, ZHP?

A. Correct.

Q. Right?
A. Can I answer more than yes or no?
Q. First start with a yes or no. Would you agree that the deviation investigation report shows that ZHP identified cross-contamination?
A. So, yes. And here's the explanation.
Q. I really just want --
THE COURT: Let him explain it.
MR. SLATER: I will, Your Honor.
THE WITNESS: So, yes. Again, this is a common practice in industry to work in campaigns of production and to minimize cleaning from one batch to the next. This is common practice. This has been going on for many years and goes on even today. So if you're making the same product and you make it, you do very minor cleaning and you move to the next batch.
BY MR. SLATER:
Q. Well, so you're not excusing the cross-contamination, you're just saying it happens sometimes, right?
A. No, I did not say that, Mr. Slater.
Q. Okay.
A. What I said was, you quoted me or you've told me that, you know, they went multiple batches and there was cross-contamination from one to the other. My response was, they were following -- actually they were following industry practice which said minimal cleaning from one batch to the

next.
Q. Well, did you read the deviation investigation report, that really thick report --
A. Yes.
Q. -- ZHP did?
A. Yes. I also read the 483 observations issued by the FDA investigator and the establishment inspection report.
Q. Great. And in the deviation investigation report by ZHP, they pointed out that they actually didn't adequately clean the machinery and that's how the cross-contamination occurred, not just between zinc chloride batches with one another, but also between zinc chloride process batches and TEA process batches, they also cross-contaminated, correct?
A. Yes. Again, I'll go back to it's the campaign of the same product.
Q. And you're saying it happens in the industry. It's a violation of cGMP to fail to adequately clean the production line and allow contamination of one drug product to get into another drug product. That's not allowed under good manufacturing practices? Yes or no?
A. From one product to another product, yes.
Q. You're actually -- all right. That's fine. I'll take that, because that's what happened here.
So that's another GMP violation by ZHP, right?
THE COURT: What is the purpose of this cross? It

needs to go to 702. This sounds like you're trying the case.

MR. SLATER: These are -- the whole point is that this expert wants to tell this jury that the drugs were not adulterated, and what I want to do is explain how his opinion is not going to be methodologically sound because he didn't take into account certain things.

And when you look at this, because he's now conceded, and I'm going to keep going, he's conceding cGMP violations before the pills ever were marketed from these new processes, he can't as a matter of law say it wasn't adulterated, because I have the statutory definition, which I'm going to get to, it meets the statutory definition of adulteration from day one.

THE COURT: Why is it that your witnesses can say that they failed to comply with cGMP and therefore they were adulterated and their witnesses can't say, well, they complied with cGMP, to the extent that there were compliance issues, they could not have known and therefore they weren't adulterated? Why -- why is that?

MR. SLATER: Because that's not what happened. The whole argument that we couldn't have known was rejected by the FDA.

THE COURT: But that's a weight argument.

MR. SLATER: But I think, respectfully --

THE COURT: That's a weight argument.

MR. SLATER: -- Your Honor, it's not a weight

argument because, as a matter of law, the FDA found that they violated the cGMPs.

THE COURT: Right.

MR. SLATER: This witness has agreed that they violated them. Knowledge is not a factor. It's the failure to do the adequate assessment. And that's why they violated cGMPs, and therefore, they are responsible -- those cGMP violations occurred, and by definition, as the FDA found in its warning letter, that meets the statutory definition of adulteration.

THE COURT: Do they have to live and die by the FDA's declaration? Can't they dispute that?

MR. SLATER: Well, he's already agreed with it, Your Honor. He agreed there was a cGMP violation; that the violations occurred.

MS. BROWN: But, Your Honor --

MR. SLATER: He's not disputing it. He's agreed.

MS. BROWN: I need to object to this mischaracterization of the testimony.

The witness testified that in November of 2018, after this had been discovered, he agrees with the then findings.

What counsel is doing and what is really amounting to his closing argument is imputing that back to 2011, which this witness was clear is not how regulations work.

MR. SLATER: That's --

THE COURT: Well, it does seem that we're -- it does seem that you are unfairly asking this witness in his answers to you to assume then what is known now. And that is why this witness is struggling to answer -- not struggling, but is pausing.

MS. BROWN: Clarifying.

THE COURT: Pausing to answer the questions, because of the way that you are phrasing the questions I think can be -- might be unfair. Because it is easy in hindsight for the FDA to make these findings. But this witness has opined, whether the jury accepts his opinion or not, is that you've got to deal with it in real time. You've got to deal with it in industry standard, what the industry knew then, what they were looking for, whether or not they knew whether even this NDMA was even anything that anybody imagined.

It's easy now in 2018 and 2019 for the FDA to say, aha. That goes to the weight of the argument. But I think you've got to be careful in your questioning that you're not confusing this witness in terms of what we now know versus what we knew then. And that's the difficulty that I'm having in following this line of questioning.

MR. SLATER: I'll try to attack that issue.

BY MR. SLATER:

Q. The FDA doesn't issue warning letters -- and this is going to sound like a very simple and obvious question, but I want to

get this on the record.

The FDA doesn't issue a warning letter for violations before the FDA knows about the violations. That would be impossible, right?

A. Correct.

Q. In every warning letter you've ever seen, the conduct that led to the warning letter occurred and that the FDA looked back and said what you did violated GMPs in situations like this. It's always a look-back in 100 percent of the cases, right? Because they don't have a crystal ball warning letter process.

A. FDA sends -- I can't answer yes or no.

Can I explain?

THE COURT: Yes; could you?

THE WITNESS: So FDA sends investigators to the facility. Investigators usually come every two years. Investigators look at what is happening on that day in the facility. They look at the records going over the past two years of what are the market complaints, what are the deviations, what are the investigations, and then FDA investigators make an assessment that, you know, what is going on today or what was going on is not acceptable. But generally, they're not actually saying based on what you did last year, I'm issuing 483 observations.

So 483 observations are issued, Your Honor, just after an inspection is complete. They issue the 483

observations, and industry then responds, the firm responds, as ZHP responded here.

FDA looks at that response and then determines that if the firm has not actually grasped the issue, they issue a warning letter. They don't issue a warning letter because of there are cGMP noncompliances. CGMP noncompliances are recorded in the Form 483.

MR. SLATER: Okay.

THE COURT: So a warning letter is not issued for cGMP noncompliance issues?

THE WITNESS: No.

BY MR. SLATER:

Q. In this case -- okay. Let me continue because I don't want to get bogged down with that.

Let's look -- I'm going to try to finish with this document, then we're going to go back to the warning letter and I think have some really good answers for some of the questions that Her Honor just asked. So let's first finish up this paragraph in the January 25, 2019 FDA statement.

A. Yeah.

Q. The next line, I had left off with the cross-contamination point. Do you see where I left off? Cross-contamination.

A. Change control and cross-contamination from one manufacturing process line to another, yes.

Q. Correct. Let's look at the next sentence.

A. Yes.
Q. Because we've had a lot of questions here about, well, should the FDA have caught this or not. Let's see what the FDA said about what happened here.
"It's unlikely that the subtle problems causing these impurities could have been found on a routine current good manufacturing practice, cGMP, inspection."
Do you see that sentence?
A. Yes.
Q. And what you had on the board before was a whole series of inspections. Those were routine cGMP inspections, right?
A. Yes.
Q. And the FDA made very clear that what happened at ZHP would not be expected to be found on those routine inspections. That's what this says, correct?
A. Again, yes.
Q. Is that what this says, yes or no? Sir, I'm not sure why it's so hard. Does it say yes or no? Is that what it says?
A. It's very different --
THE COURT: It says what it says.
THE WITNESS: Yes.
THE COURT: I mean, we have to quarrel about what it says.
THE WITNESS: Yes, it does say that.
MS. BROWN: Your Honor, I object. Respectfully, this

goes to weight. I mean, counsel is --

THE COURT: I know, it does. I know, but -- it does.

MR. SLATER: And --

THE COURT: It does.

BY MR. SLATER:

Q. Well, and then they say, to finish this, "Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise." That's the conclusion to this paragraph, right? Correct?

A. That's the conclusion to the paragraph.

Q. Okay. So you had talked a lot about the FDA's role. The FDA did not say that, well, you know, we missed it. They said we wouldn't have been expected to catch this. That's what they said. That's a fair paraphrase of this, right? Is that a fair paraphrase?

THE COURT: On the warning letter? What are you talking about?

BY MR. SLATER:

Q. On the sentence I just read, you would agree that the FDA's position was, we wouldn't be expected to have caught this on our routine inspections? We just went through that, right?

A. So FDA is saying -- yes, that's what the language is. But I think, if I may be bold enough to say, you're taking one sentence out of four pages. So, yes.

Q. Let me -- but you did say before -- and there's no opinion

in your report I've ever seen, and you just agreed, you're not saying the FDA is at fault, missed this, should have caught it, you didn't ever give that opinion, right? Am I correct? Yes or no?

Am I correct?

A. Yes, you're correct.

Q. Okay.

A. And I disagree with my "yes, correct" answer because it needs an explanation.

Q. Okay. Let's go back now to the warning letter, please.

A. Okay.

MS. BROWN: May he be allowed to explain, Your Honor?

THE COURT: Is there a dispute among the parties that the FDA perhaps was not doing its job? Is that disputed?

THE WITNESS: No.

MR. SLATER: We're not --

MS. BROWN: As I understand it actually, Your Honor, they moved in limine to prevent us from blaming the FDA, and nobody's blaming the FDA. I mean, the facts are the facts. There are statements that they made about knowledge.

THE COURT: Well, okay, so then why are we talking about this?

MS. BROWN: I don't know.

MR. SLATER: Well --

THE COURT: I would just make a, I suppose, a note,

it seems from an objective bystander that, you know, the FDA probably was a little not doing its job. But, you know, if it's not an issue, then let's move on.

MR. SLATER: That's why I moved in limine, because I didn't want them to try to suggest to the jury, well, don't blame us, the FDA let this happen.

THE COURT: I'm not so sure that anybody has to suggest it to the jury.

BY MR. SLATER:

Q. Now, let's go back to the warning letter, if we could, sir.

A. Yes.

Q. We're back on page 4 under Deviation No. 2, the second paragraph under that.

"You also failed to evaluate" -- failed to evaluate -- "the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change."

You see what I just read?

A. Yes.

Q. So, again, they're saying you should have evaluated it but you didn't. That's what this means, right?

A. Sure. Yes.

Q. And then they said, "you" -- meaning ZHP -- "are

responsible for developing and using suitable methods to detect impurities when developing and making changes to your manufacturing processes."

Do you see that?

A. Yep.

Q. And you agree with that, right?

A. I do.

Q. Okay. And, in fact, let's make sure that we all understand this, and for the Court's benefit, ZHP did not create the manufacturing process for Diovan. They copied it with the TIN process, right?

A. Yes.

Q. And that TIN process, based on the chemicals used, it would have been impossible to create NDMA because there was no chemicals in that process that could combine to create any nitrosamines. You're aware of that, right?

A. I'm the regulatory expert. You're asking me a chemistry question. So --

Q. So you don't know?

A. As a regulatory, I believe if there was no NDMA in the other process, then it wouldn't have been here. There was no NDMA found in the original process at ZHP, so...

Q. Right, which was a copy of the Diovan process.

A. Yes.

Q. So then what ZHP did is they said, well, we're going to

change the process because we want to make a lot more a lot cheaper so we can sell it cheaper, that's good for market share and that's good for business. That's what happened here, right?

THE COURT: Mr. Slater, either you're making your opening or your closing argument. What is the 702 objection?

MR. SLATER: The 702 objection is that my sense was that there was a -- my sense was that the Court may have had the feeling that, well, even though they violated cGMPs, it may not be the type of violation that would rise to the level of adulteration. So what I'm trying to do is make an ironclad record that that's actually not the law. The law is if you violated cGMPs, it's absolutely adulterated by definition. And what I'm trying to do is also answer a lot of the points this witness made on direct where he was trying to be allowed to testify. And these next couple paragraphs answer a lot of the Court's questions.

THE COURT: Well, assume for a moment that you are correct, that is -- because this case involves issues of knowledge, issues of fraud, what ZHP knew, didn't know, what ZHP did, didn't do, this witness's testimony goes to that. That's perfectly permissible.

Whether or not his testimony somehow is erroneous as a matter of law because a drug is adulterated if there are noncompliance issues is easily resolved by a jury instruction.

But he should be permitted to testify what ZHP did, what ZHP didn't do, whether they followed the proper protocols, et cetera, because you have a fraud claim.

MR. SLATER: And we have -- and I agree. And I think ultimately what this witness should be allowed to do is talk about what ZHP did.

THE COURT: Of course.

MR. SLATER: I don't think he should be allowed to -- well, I don't -- well, now he's not giving the opinion. When I walked into the courtroom, I thought he was going to say they didn't --

THE COURT: I know you did. And I'm not so sure that he is.

But what I am ruling on is that you can't have it one way, okay, and you want to brief the issue, brief the issue, so that the jury is not misled. But I can't have a plaintiff's expert opining as to a matter that the defendant's expert is not permitted to opine as to.

If that creates, as a matter of law, error, you'll tell me. But I will instruct the jury if the law is that if it's a noncompliant, if there's a breach of cGMP, then by definition it's adulterated, period, end of story. That's the law.

But I'm not going to let, you know, your witness say one thing and not the other witness.

MR. SLATER: Well --

THE COURT: If the facts are disputed.

MR. SLATER: I think -- and I was -- I think what's happened, and, again, I didn't anticipate it, is that I thought there was going to be a dispute as to whether there was a violation of GMPs. Now I found out there's not. There's been a concession that GMPs were violated.

I get he's trying to say, well, looking back I agree, but that's a meaningless qualifier.

THE COURT: No, it's not, because you have a fraud claim.

MS. BROWN: Right. Exactly.

MR. SLATER: Well, then I'm making --

THE COURT: ZHP is entitled to defend itself. You can't just stand before the jury and say, aha, they violated cGMPs so case over.

MR. SLATER: Oh, I'm not basing -- our fraud claim is not based solely -- just on the mere violation of cGMPs.

THE COURT: I understand that.

MR. SLATER: Yeah; it's different.

THE COURT: But it's all part of the -- what they did, what they didn't do, and it's all part of what they knew, what they didn't know. That's all relevant to me.

MR. SLATER: This is what I suggest I'll do. I want to go through the next paragraph because it directly addresses

the issue of whether they should have known or not to look at this. I'm going to clean that up and then I'm going to move right to the email.

THE COURT: Well, I'm going to shortcut it. I think that he's more than qualified to opine in terms of a regulatory context about what the standard is, about what would have been reasonably expected to have been found.

And so you can cross-examine him on, you know, why they did or why they didn't, but that goes to the weight. That goes to weight.

Did you want to say something?

MS. BROWN: Yes, Your Honor. And I did just want to say, counsel continues to characterize the warning letter as having this retroactive implication; that because they say in November 2018 we have now, knowing what we know, found violations, somehow that means back in 2011 --

THE COURT: I don't know. This witness testified that a warning letter doesn't go to compliance issues. It's a jury question.

MS. BROWN: That's what I would just suggest, Your Honor.

THE COURT: It is.

MS. BROWN: This is an issue of fact for the jury that his folks can get up and say, sure does, look at the warning letter, and we can have the opposite.

THE COURT: He just said that. So it will go to the jury.

MS. BROWN: Thank you, Your Honor. I appreciate it.

MR. SLATER: I have to be honest, I don't understand that distinction, but I'll keep going through. I don't understand the distinction. The warning letter went to what they did here, and that's what renders the drugs adulterated.

MS. BROWN: The interpretation of that letter is an issue for the jury that will come in through two different parties' regulatory experts.

THE COURT: Right.

MS. BROWN: Thank you, Your Honor.

BY MR. SLATER:

Q. Let's look at the next paragraph.

"Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with cGMP requirements and that you are responsible for the quality of drugs you produce."

You agree that that's an accurate statement of the regulatory law, correct?

A. That is a statement made by FDA in its warning letter, sure.

Q. It's accurate, right?

A. It's accurate. May I give you --

THE COURT: Yes.

THE WITNESS: Yeah, it is accurate. It is what it says there.

At the time of the formation, of the creation of the process, the regulatory requirements were very different than at the time when this observation was made, and therefore, this warning letter was issued.

BY MR. SLATER:

Q. So let's talk about your methodology on knowledge --

A. Yeah.

Q. -- what we just talked about.

Your methodology is, I looked at everything and I don't see anything indicating that ZHP ever actually knew that NDMA was or could be created by its zinc chloride manufacturing process before June of -- May of 2018? That's what you said, right?

A. Yes.

Q. Okay. And implicit in that is ZHP didn't know, according to your methodology of reviewing everything you saw, that the chemical reactions that led to the creation, they didn't know about those chemical reactions yet because, and you explained why they didn't know it, but your methodology is I'm assuming they didn't know, even that, for example, DMF could degrade to

give off dimethylamine. They didn't know that either. That's what you're assuming, right?

A. That's what I'm stating based on the regulatory statements from FDA.

Q. Okay. And as part of your methodology, did you expect that the lawyers who hired you would give you any ZHP documents that showed, if they actually existed, that ZHP did know before May of 2018 that DMF could degrade and give off dimethylamine? Did you assume that they would have given you those documents so you would have been aware of that?

A. I --

THE COURT: Can you rephrase the question so that you're not casting aspersions toward counsel?

MR. SLATER: Sure.

BY MR. SLATER:

Q. Did you assume -- well, rephrase.

Did you expect that if there were any internal documents from ZHP that showed that they knew before May 2018 of these potential chemical reactions like the DMF degrading to give off dimethylamine that you would have been provided those so you could incorporate those in your opinion?

A. I -- yes.

Q. But you didn't see anything like that other than potentially the email, but we'll talk about that, you don't agree that that means they knew, right?

A. Correct.
Q. Okay.
MR. SLATER: May I approach, Your Honor?
THE COURT: Okay.
(Handing out documents.)
THE WITNESS: Thank you.
THE COURT: Thank you.
BY MR. SLATER:
Q. What I've just handed you is a document titled: "Report on the Investigation of an Unknown Impurity at RRT 0.34 in Related Substances Testing of Losartan Potassium." And the Bates number is ZHP02908569.
Do you see that?
A. Yes.
Q. And do you see who it was prepared by?
A. Yes.
Q. Who was it prepared by?
A. It was prepared by Jinsheng Lin.
Q. The same person who wrote the email in July of 2017 we've talked so much about today, right?
A. Correct.
May I add something, Your Honor?
THE COURT: Well, you can do that on redirect.
THE WITNESS: Okay.
THE COURT: Go ahead.

BY MR. SLATER:

Q. And now let's look at page -- I'm going to use the Bates number. It's page -- it doesn't say of 9. Go to the Bates number where the last two digits, please, are 74.

A. Yeah.

Q. So it's about eight pages or so in.

A. Yeah.

Q. And he's talking about this impurity that he's seeing in a losartan study he's doing, and he says the following: "The possible generation pathway of this RRT 0.34 impurity is as follows: First, DMF is used as a solvent in the condensation process and potassium carbonate is used as the acid binding agent in the reaction."

"Under heating conditions, DMF will decompose to produce dimethylamine." And then, "dimethylamine reacts with protective group bromide," et cetera.

Do you see what I just read?

A. Yes.

Q. So this shows that in a report written by Jinsheng Lin in November of 2017, he actually talks about the fact that DMF under heating conditions will decompose to produce dimethylamine. That's what the words say on the page, correct?

A. Yes.

Q. You've never seen this before, right?

A. I saw this last week.

Q. You saw this last week?
A. I saw this last week.
Q. Did you supplement your reliance list to tell us you saw this document? I didn't see a supplemental reliance list.
A. So --
Q. I'm just asking, did you do a supplemental reliance list? Yes or no?
A. No, because --
Q. Okay. I just asked you if you did, sir. I may not even go to the place you think I'm going. I may not be that clever, so.
A. No, no, no. No, I didn't update it because my report which has been submitted is not relying on this.
Q. Well, I wouldn't think it would be.
THE COURT: Okay. What's the question?
BY MR. SLATER:
Q. So you actually saw this document a week ago?
A. Sorry, sorry. Allow me. Allow me. Maybe I need to correct myself. Let me see.
No, I have seen this report. I have seen this report. I have seen this report. That was a mistake that I said I saw this last week. No, I've seen this report before, yes.
Q. You've seen it even before last week?
A. Yes.

Q. When did you see this report for the first time?
A. I don't remember when I saw it first time, but it would have been in my documents, which I reviewed.
Q. Did you see this document when you wrote your report?
A. Yes.
MR. SLATER: I have another one, Your Honor. Only two of them.
MS. BROWN: Your Honor, I'm just going to object to no 702 --
THE COURT: Yeah, this is -- I'm going to -- I'll probably put an end to this, Mr. Slater, because this is sounding like a weight --
MR. SLATER: I think -- well, what I'm trying to get at is that his methodology is completely faulty, and I want to see what --
THE WITNESS: No.
MR. SLATER: And I want to understand how he reconciles the fact that we now know he had this document when he wrote his report and never mentioned it and didn't talk about it and never expressed how this factors in.
THE COURT: Wait. He wants to correct the record. What do you want to say?
THE WITNESS: I don't believe I saw this till last week, either of these documents.
MS. BROWN: Here's what happened, Your Honor. He

responded to plaintiffs' experts. Plaintiffs' experts did not rely on these documents. A week ago they produced translations to us about these documents. We gave them to Dr. Afnan and said does it change your opinion.

He's not relying on them because he's -- his job is to critique plaintiffs' experts. They didn't --

THE COURT: Why are you just now getting these a week ago?

MS. BROWN: These are losartan documents that have to do with a totally different medicine. And so we asked him does it change your opinion, he said no. The original experts he's responding to don't rely on it. He's had -- this is all cross, in any event.

MR. SLATER: Well, actually it's not, because I wasn't given these documents till this year. They were -- this -- the documents --

THE COURT: This is losartan, though.

MS. BROWN: Correct.

THE COURT: So what are we doing here?

MR. SLATER: This is showing that the company and Jinsheng Lin who wrote that email knew about these chemical processes that led to the formation, which their position is no one knew it till May of 2018, his email couldn't mean what it says. And this is showing that that's not true. And his methodology is completely faulty, because the fact that he knew

about this and didn't grapple with it in his report --

THE WITNESS: No, no, no.

THE COURT: So you're trying -- hang on.

MR. SLATER: And this goes to the knowledge issue that Your Honor was concerned about.

THE WITNESS: Sorry, Your Honor. I didn't see this until last week, so how can I put this in my report if I didn't see it until last week?

MR. SLATER: That's okay. But you didn't talk about it on direct when you were questioned today, right?

THE COURT: Mr. Slater, would you mind if I said a few words?

MR. SLATER: I'm sorry, Your Honor. I didn't really -- I certainly don't mean to interrupt you. I'm sorry.

THE COURT: It seems to me you are taking these documents and you are attempting to impeach this witness on his reliance on a document that you intend to impeach through another witness. So this is impeachment three times removed, something like that.

So you want to impeach the email that he relied upon and the translation that he gave -- this is how I'm understanding it -- through these documents.

These documents go to another witness.

MR. SLATER: I --

THE COURT: Okay. If his reliance on an email, his

reliance on a document falters by another means, so be it. But you can't circumvent the process and try to impeach that witness through this witness.

MR. SLATER: If you could just give me about a couple more minutes to finish this, I would think --

THE COURT: I think my patience has run thin.

MR. SLATER: I -- the question that I'm building up to, I would expect that his answer would be that he's going to withdraw his opinion if he has a credible methodology. And if he doesn't withdraw his opinion based on the questions that are coming, I think his methodology would be faulty on his assumptions about what the company knew and didn't know. He made assumptions knowing this and ignored it.

THE COURT: He just --

MR. SLATER: And I don't think --

THE COURT: He just said that he became aware of this a week ago; it does not change his opinion.

MR. SLATER: Now can I show him the second one and see maybe if he sees a second document that --

MS. BROWN: It's exactly the same, Your Honor.

MR. SLATER: If there's a second document that helps him to reconsider his testimony.

THE COURT: Give it a try.

MS. BROWN: But, Your Honor, it's exactly the same.

THE COURT: Let's just give it a try. Sometimes it's

just easier to just give it a try.

MS. BROWN: Okay. Same objection for the record, Your Honor.

THE COURT: I know. And I'm about ready to make my ruling. So ask your question, give your answer, and I'll give you my ruling.

BY MR. SLATER:

Q. So looking at the next document, it's a report on an impurity at RT 16.9 minutes. Do you see that?

A. Which page am I looking at?

Q. I'm just looking at the cover right now. Do you see that document?

A. This one?

Q. And it's dated January 15, 2018?

A. Yeah.

Q. And you see who reviewed it, at the last signature?

A. The last signature, Jinsheng Lin, yes.

Q. Okay. And if we go now to page 6 of 21, the page numbers are in the top right. And the Bates numbers, for the record, of the first page was ZHP02929237.

If you go to that page and you work your way down about two-thirds of the way down, right just above where you see in bold, it says "Scheme 2." You see the word "Scheme 2" in bold?

A. Yes.

Q. Just above that to the right of it, it says "we."

"We checked the production process flow chart of losartan potassium API in which DMF is used."

DMF is the same solvent that led to the NDMA formation in the valsartan that we're talking about today, right? Correct?

A. Yes.

Q. And it says, "And DMF is likely to be hydrolyzed to produce dimethylamine."

Hydrolyzed means when water reacts with it, it will give off the dimethylamine, right?

A. Yes.

Q. So this shows that well before May 2018 -- and you don't know how far back it goes -- ZHP did know about the chemical processes and impurities that could come off of DMF, specifically the dimethylamine could be formed. They knew that long before you have told the Court and you ever said in your report, they knew that, correct?

A. Are you asking me to opine on your opinion on this?

Q. I'm asking factually.

Will you acknowledge that they knew before May 2018 that these chemical processes could occur with DMF?

A. I -- Mr. Slater, I have not seen this. I got this on Thursday of last week, right?

THE COURT: Okay. I'm going to sustain the

objection.

I think it goes to the weight of the evidence. I think it's circuitous. I think you're trying to -- here's how I see it, and this is how I see it. This witness is testifying -- let's say this witness testified. I'm trying to write the syllogism down as I'm thinking it.

He relies upon a document in his expert report. That document says it was raining on the day in question. There are other documents out there that somehow show that it was sunny that day. He has rendered his report based on the fact that he believed it was raining. If the jury discredits that assumption by whatever means, so be it. The jury may discredit that assumption or they may credit his assumption, but that's a jury call. And this is a weight cross-examination.

So simply because the plaintiff believes that these are aha documents will show that that email that the witness relied upon, that's going to be a jury question. You're not going to -- he's already said he hasn't seen them, he saw them a week ago and it hasn't changed his mind. I think it stops there.

MR. SLATER: Obviously I'll stop there. If Your Honor's instructing me --

THE COURT: Yeah.

MR. SLATER: -- I'm certainly not going to keep asking the questions.

BY MR. SLATER:

Q. Do you agree the contaminated valsartan pills should not have been sold?

A. Absolutely.

Q. Okay. You'd agree from day one they never should have been put on the market, right?

A. So any firm who finds its product is contaminated with something as nasty as a mutagenic product should stop release, and ZHP did that.

Q. Well, you opined in your report that they did it as soon as they knew about the contamination. In May of 2018 you said they knew.

A. June. June 2018.

Q. Your report says in about six different places they first knew about the risk of NDMA in May, right?

A. May is when Novartis wrote to them and said please give us explanation of this peak.

(Court reporter clarification.)

THE WITNESS: A peak of impurity.

BY MR. SLATER:

Q. And, by the way, all the regulatory guidances that governed here, ICH Q3A, ICH Q7, the FDA 2008 guidance, all of those were in effect before ZHP was actually manufacturing the valsartan at issue here for sale. Those were already in place, right?

A. Correct.
Q. So there was no change to the regulatory scheme later?
A. No.
Q. So that the rules got changed. The rules were the same then as they are now, right?
A. Correct.
MR. SLATER: Your Honor, just bear with me. What I'm trying to do is pick through a little and try to find things that there still may be some patience for.
THE COURT: There what?
MR. SLATER: That there still may be some patience for.
Much as I love to try to become --
THE COURT: I don't know, Mr. Slater.
MS. BROWN: Just leave all the stuff that goes to weight.
MR. SLATER: Okay. I will.
BY MR. SLATER:
Q. The July 27, 2017 email, just to be clear --
A. Yes.
Q. -- everything that Jinsheng Lin said in there is accurate. There was NDMA in valsartan. It was formed by the sodium nitrite quenching, and it was a cGMP problem, and it was a problem with sartans across the board, right? Those are all true statements, correct?

THE WITNESS: Sorry, Your Honor, I can't give a yes-or-no answer.

THE COURT: Okay.

THE WITNESS: So the answer is no. That is an email in Chinese which has been translated several times. It also talks about, as I read it, it refers to a patent. The patent is about formation of nitroso products in irbesartan, a different product, and that it says these are similar to Impurity K.

BY MR. SLATER:

Q. Did you read Min Li's deposition testimony talking about the email?

A. Yes.

Q. Do you know who Min Li is?

A. I don't remember exactly what his title is, but, yes.

Q. He's Jinsheng Lin's boss. He ran CEMAT, the technical division that did all the analysis of impurities at ZHP.

A. Okay.

Q. Does that refresh your recollection?

A. No. But carry on, please.

Q. He's a Ph.D. chemist from Johns Hopkins who's bilingual. Do you know that? Did you read that in his deposition?

A. Yes.

Q. And did you see in his deposition that I actually went through the email with him and he told us what it said? And,

by the way, did you see that?

A. I --

Q. Did you see in the deposition I went through it with him?

A. I do not remember.

THE COURT: See, this goes to weight. Okay. He can assume, he can assume whatever he assumes. He can assume the letter said this, he can assume the letter said that. That's what he relied upon. It's then your job on cross -- it doesn't mean that his methodology is wrong. It doesn't mean that what he -- that he doesn't have the expertise. You are then permitted on cross. It goes to the weight of the evidence that the jury gives it.

MR. SLATER: Except if he's relying on inadmissible evidence. So let's talk about what you rely on.

THE COURT: You don't intend to introduce that email?

MR. SLATER: No, no, I'm talking about the basis for his opinion that it doesn't say what it says.

THE COURT: Well, that's how he interpreted it.

MR. SLATER: But let's talk about how he reached that interpretation, because I don't think he has a valid reliable basis on which to give that opinion. I think he's just saying it and it's just ipse dixit conclusory, I just want to say it. And let's talk about that.

BY MR. SLATER:

Q. Number one, Dr. Xue --

A. Yes.
Q. -- you're not relying on him?
A. I'm not.
Q. And you know his opinions on what the email said have been precluded at trial. Do you know that?
A. Yes.
Q. Okay. So you can't rely on that.
You relied on your conversation with Jucai Ge who told you what Jinsheng Lin told her, right?
A. No. The email is addressed to her, so --
Q. It was -- go ahead. I'm sorry. I didn't mean to interrupt you.
A. So the email is addressed to her. She read the email. I said, does the email say this? This isn't any hearsay of what was your conversation. My question to her was, does this email say that there was NDMA in valsartan?
Q. Did you see her deposition, her sworn deposition as a 30(b)(6) witness where she said, yes, that's what the words say, it says there's NDMA in valsartan? Did you see when she testified under oath to that?
MS. BROWN: I object. That's a mischaracterization of her testimony.
THE WITNESS: No. No, I did not, because I did see -- sorry.
MS. BROWN: No.

THE COURT: No. Go ahead.

THE WITNESS: Sorry, Your Honor.

THE COURT: Go ahead.

THE WITNESS: I did see also that you asked her a question does this -- is this correct, and she said, no, it's not. We did not know about NDMA in valsartan.

BY MR. SLATER:

Q. Right. She said the email says there's NDMA in valsartan, and then she also said, but we didn't know about it, because she said that nobody paid attention to the email. Did you see that part?

MS. BROWN: Your Honor, I object to all of this. It goes to weight.

THE COURT: Sustained.

MR. SLATER: Well -- okay.

THE COURT: So this is all weight, all, all weight. All weight.

BY MR. SLATER:

Q. So you're relying on Jucai Ge's reading of the email as to what it says?

A. Yes.

MS. BROWN: He's asking the same question.

THE COURT: Sustained. We've been around about it.

MR. SLATER: I just want to make sure I understand, because I'm going to have an issue, Your Honor, if she's going

to now --

MS. BROWN: But it was sustained.

MR. SLATER: I guess we're going to have to lay it out for Your Honor before the evidence comes in, but Min Li was the 30(b)(6) witness --

THE COURT: Yeah.

MR. SLATER: -- who I asked about it and said what it said. So are we now going to have two different 30(b)(6) witnesses come in and contradict each other about the meaning of this? I don't think that would be permissible.

THE COURT: What do you mean two 30(b)(6) witnesses come in?

MR. SLATER: Jucai Ge --

THE WITNESS: Says no.

MR. SLATER: -- he wants her to come in and say it didn't say this when Min Li already said it does say this.

THE COURT: Well, then that's not -- that's their issue, not yours.

MR. SLATER: All right. So I understand --

THE COURT: But this witness -- Mr. Slater, this witness relied upon the email. He spoke to the recipient of the e-mail. He asked the recipient how did you interpret this. And based upon that, he came to the conclusions he came to.

You may cross-examine him. You may cross-examine him to show that his reliance was ill-conceived. But it doesn't

mean that he couldn't rely on it.
BY MR. SLATER:
Q. Are you solely relying on what Jucai Ge told you the email said?
A. As I said earlier today, I looked -- I spoke to her. I read her testimony. I studied the patent which is attached to that email, and I read the email as well, so -- and there are other translations of the email. So there were a number of activities that went on. No, I read the email. I read the patent which is attached to the email.
Q. Did you read the translation that ZHP provided in discovery?
A. I've looked at multiple translations.
Q. Did you see that the translation ZHP provided said there's NDMA in valsartan and it's caused by the sodium nitrite quenching?
A. I don't know who had provided that translation.
THE COURT: You considered differing translations; is that what you're saying?
THE WITNESS: Yes. But they're very different, Your Honor.
THE COURT: Okay.
MR. SLATER: Sorry, Your Honor. I'm having a paper overload issue.
THE COURT: Join the crowd.

MR. SLATER: Ah.

(Handing out documents.)

MR. SLATER: This is the ZHP translation attached to former counsel for ZHP's certification.

THE WITNESS: Thank you.

MS. BROWN: Your Honor, I object. This goes to weight.

THE COURT: Okay. Mr. Slater, you can show him 25 different translations, okay. He relied upon varying translations. He then rendered his opinion based upon the translations he chose to rely upon. You can show him different ones. They all go to weight. It is not -- it is not impermissible for an expert to rely upon certain documents and to disregard others. That goes to weight. There's nothing under the law that says an expert has to consider everything -- everything possible. Those go to weight.

But I find his testimony was -- that he had the specialized knowledge. His testimony was the product of sufficient facts. He relied upon various documents that were given to him through the course of the litigation. I find that his testimony has been reliable. But all of the cross-examination thus far has gone to weight.

MR. SLATER: My concern, Your Honor, is that Your Honor has talked about your role as a gatekeeper under 702.

THE COURT: Yes.

MR. SLATER: That if the witness wants to say, well -- there's only two translations, by the way.

THE COURT: Okay.

MR. SLATER: There's ours and ZHP's, and they both say the same thing on these points.

THE COURT: Well, I don't think that's the case. I don't think this witness --

MR. SLATER: Well, I can show them to Your Honor, because my concern is that I don't think the witness can say -- even if the sentence says exactly what it says, for him to say, well, I don't agree that it says what you can see it says.

THE COURT: But then he spoke with the recipient of it as well. And so what do you want me to do about it, Mr. Slater? I mean, that all goes to weight.

You can show that he was -- his testimony should be given no credibility because he relied -- you know, that he called the recipient and it's black and white, it says what it says. Or why did he bother looking at the patent that was attached to it? That was a side event. He should never -- whatever it is the cross you want to do. But that goes to the weight of his testimony.

MR. SLATER: I hear Your Honor.

So you know, Min Li also received it. It was sent to multiple people. He explained what it said. My concern is, as you understand, is that the witness is going to come in and

even though every -- everybody said it says this. For the witness to come in, who doesn't speak Chinese, he can't read it himself, and to say, well, you know what, I just interpret these words differently, I don't think the Court can let him go that far when it's black and white, every single person said it said this. Their only explanation is, well, he didn't really mean it or he was guessing.

THE COURT: Are you not turning me into a fact finder?

MR. SLATER: I don't -- I -- it's interesting because the defense was arguing in the *Daubert* hearings a week or two ago that 702 has been amended, so you now have to actually look into this and see if there's a reliability factor to a conclusion. So I was just following through with that. That was what I was doing.

THE COURT: And I'm finding that it's reliable. Whether the jury finds it or not is up to you, Mr. Slater, to attack on cross-examination, as you've been attempting to do.

Yes.

MR. SLATER: I understand.

MS. BROWN: And, Your Honor, your role as the gatekeeper is to say did you rely on reliable information. Did you call someone? Did you look at something? The Court has fulfilled that. All of these questions are --

THE COURT: Yeah.

MS. BROWN: -- you looked at this, you didn't look at this, everybody said this, what about this, it's all weight.

THE COURT: They go to the weight.

MR. SLATER: I got it.

THE COURT: If this witness were testifying that he relied upon an email that his sixth grade teacher wrote --

MS. BROWN: Correct.

THE COURT: -- I mean, then we would have an issue.

MS. BROWN: Correct.

THE COURT: But this is a document that was produced in the ordinary course of the litigation, in the ordinary course of ZHP's business and he has interpreted it as such.

MR. SLATER: Fair enough. I understand, Your Honor. I'm not going to ask any more questions about this subject.

THE COURT: Okay. Does that mean you're done?

MR. SLATER: No. Now I have to go to the last part which I think is very significant, but --

THE COURT: His reliance on Xue?

MR. SLATER: His reliance on Xue. It's all over. I can walk through paragraph after paragraph to show you that what he said he did not form an opinion on, which is what could have reasonably been known --

THE COURT: I find his testimony credible that he didn't know it until the night before.

MR. SLATER: Oh, no, no, no. I'm not talking about

that issue.

THE COURT: What are you talking about?

MR. SLATER: Oh, no, I get that. What I'm saying is --

THE COURT: And so to the extent that you want to strike paragraphs 140 and 191, those two paragraphs, you know, I'm not going to, no. He's permitted to testify to those. 141 and 190.

MR. SLATER: But Dr. Xue has been precluded. Those opinions that he's relying on have been barred.

THE COURT: Well, he doesn't -- that doesn't mean that he -- it doesn't mean that he necessarily can get on the stand and say, oh, and by the way, Dr. Xue said that.

MR. SLATER: But his reliance, if you go through this, what I think permeates these paragraphs, I think we're probably at the argument part on this point, because I could go through it with him, and I think I can go show Your Honor if I walk through it that every one of these opinions relies on the fundamental opinion of Dr. Xue that nobody could have reasonably known this so there was no reason to look for it.

THE COURT: He testified that he didn't even review Xue's report until the night before he wrote his report.

MR. SLATER: But with --

THE COURT: And so that -- that ends it.

MR. SLATER: But without Xue, he can't give the

opinion because he's not a chemistry expert.

THE COURT: He can't give what opinion?

MR. SLATER: He can't give the opinions -- any opinion that's based on what ZHP should or shouldn't have known or could have known from a scientific chemistry standpoint, because he's not an expert in chemistry, all these opinions we listed here are bottomed on the opinion that this was not reasonably knowable. And he's not qualified to give that opinion.

THE COURT: But you don't need to be a chemist to make that --

MS. BROWN: Right. The FDA --

THE COURT: You don't need to be a chemist to make that opinion.

When I read these two paragraphs, you can easily strike out "as explained in detail in the report of Xue." I mean, it was not necessary for him to write that. He made an independent determination based upon his regulatory experience. He didn't need to write it. Why he did, I don't know. But he probably felt like, oh, I have someone who's bolstering my argument. Xue's been precluded so he's not going to be permitted to say to the jury, oh, by the way, you should know Xue said the same thing to me.

MR. SLATER: Except he didn't do the analysis, Your Honor.

THE COURT: I find that he did.

MR. SLATER: But he didn't look at the science -- I'll ask.

BY MR. SLATER:

Q. Did you do an analysis of scientific chemistry literature and talk about it in your report as to what was known at the time? I didn't see it in your report. Is it there? Yes or no?

A. My --

Q. It's simple, did you do an analysis in your report --

A. I was --

Q. -- on the state of the scientific organic chemistry literature that was available to be known to ZHP when they were developing this process? Yes or no?

A. I was the regulatory expert responding to your experts.

MR. SLATER: So how can he give an opinion on what could have been known in the chemistry literature among the chemistry community if he's not an expert in that field? He didn't do the analysis, and the witness that his report says he relied on for it has been precluded on that opinion. He has no basis for the opinion.

MS. BROWN: May I be heard, Your Honor? He is offering the regulatory opinion, what does the regulatory records say. And the FDA told the American public and the world: We didn't know. Industry didn't know. Nobody knew.

His opinion is based on an analysis of the regulatory statements, FDA's actions, FDA's inspections. He's not going to say: All organic chemists knew this, didn't know this, look at this article, look at that.

He's saying from a regulatory perspective, this is the knowledge, these were the conclusions, these were the responsibilities, and these were the actions. It's a total disconnect between what he's arguing.

THE COURT: What she said.

MR. SLATER: For the record, I object. But I understand your ruling. And based on where we are now, I have no further questions.

THE COURT: There was one question you wanted. I said you could do it on redirect. Do you wish to do it?

THE WITNESS: No. Thank you. Thank you, Your Honor.

THE COURT: You may step down.

MS. BROWN: Excellent.

THE WITNESS: Thank you.

THE COURT: All right.

MS. BROWN: Thank you, Your Honor.

THE COURT: All right. Just please watch your step stepping down. And please collect the exhibits, counsel.

MS. BROWN: Of course. May I approach, Your Honor?

THE COURT: Yes.

(Witness left the stand.)

THE COURT: Mr. Slater, you have things up there, too.

(Discussion was held off the record in open court.)

MR. SLATER: Your Honor, I don't know if this needs to be on the record. I realized that I did not mark any exhibits yesterday, and I didn't do it again. I realized it in the shower this morning. And I'm sorry. That's why --

THE COURT: Yeah. We should have, yeah.

MR. SLATER: We might be able to do that.

THE COURT: The Bates number. Or you can just stipulate to it.

MR. SLATER: We can stipulate to exhibit numbers, just to clean up the record, that's fine.

THE COURT: Yes. Okay.

MR. SLATER: I'm sorry about that.

THE COURT: All right. No worries.

MR. SLATER: My bad.

THE COURT: Okay. So where are we?

So you have my ruling. I think that this testimony comes in.

I'm still mulling over Conti. I think -- do I owe you any other rulings? I'm going to talk about a trial date.

MS. BROWN: No, thank you, Your Honor. I think we're caught up on the rulings. Thank you.

THE COURT: Okay.

So your brief is in tomorrow? Today? What's today? Wednesday.

MR. SLATER: I'm sorry. Today, I think. Is today Wednesday? I lost track. Yes. We said Wednesday. So are we ready to file it tonight or do we need another day?

MR. STANOCH: I'd have to check, Your Honor. Today or tomorrow.

MR. SLATER: We have a team of people pulling cases, doing a massive survey, and they worked very late last night. So --

THE COURT: Okay.

MR. SLATER: We're trying to get you what you need.

THE COURT: Appreciate it. And then you'll respond on Friday.

MR. OSTFELD: Your Honor, if we're going to be responding to a massive survey, I would ask that we have until Monday.

THE COURT: No, I'm not going to give it to you. You've got to read it first and then tell me. Because you know what the issues are, okay?

MR. OSTFELD: Understood, Your Honor.

THE COURT: All right. And if I get an email from you folks or something on the docket that you all can't agree, I'm going to like do another sigh; I know I am. All right.

MR. SLATER: Nobody wants a sigh.

THE COURT: Okay. So the trial, I think I'll start picking the jury the end of October.

There's one day that's problematic for me, but I'm going to see if I can reschedule a bunch of things.

So I'm going to pick the jury on the 28th, because I have to send out this form to the jury pool and then they complete it, so I have to prequalify.

So I think if I give you folks -- if I start on the 28th, we definitely will get the jury by that week. If not, and then if we have the jury, we're going to go right into openings. We're going make use of the time. So the 28th, 29th, 30th, 31st, and the 1st.

There is one date, let me look at my calendar here, that's a little iffy.

Yeah. The 29th is a little iffy, but right now I want you to assume that we're going to sit that day, okay?

So where are we with the questionnaire? Oh, you all went back to take another look.

MR. SLATER: I'm waiting to hear back. I think counsel for the defense was going to modify it or -- if there's anything to talk about, obviously we're available.

THE COURT: Okay.

MS. LOCKARD: Yeah. We'll work it out, Your Honor.

MR. SLATER: I have plenty of time.

MS. LOCKARD: Is there a date by which you need that?

We will obviously get to it. But --

THE COURT: Well, no, I'm fine. I mean, just not, you know, I need a bunch of copies and all of that, so I'm fine. And I don't think there was too many questions I had issues with, so...

MR. SLATER: You ruled on a couple of them, too.

THE COURT: Yeah. It would be helpful if there were any -- just show me the ones that I need to rule on, if you can't agree.

MS. LOCKARD: I think you ruled pretty clearly. And I think we know where we need to go on that. We just need to, I think, finesse the language in a way -- I think Mr. Slater and I can reach an agreement on that.

THE COURT: Okay. Yeah. It would be great if you don't have any other disagreements on the voir dire.

MS. ALLON: Your Honor, I'm sorry, just on availability on that week.

THE COURT: Yeah.

MS. ALLON: When we originally set the dates I think I mentioned to this Court I have a conflict on October 31st. We were going to do jury selection, I was going to miss that day. It's my brother's wedding. Like, I'm going to be disowned by my family.

MR. SLATER: Congratulations.

MS. ALLON: Thank you.

So I understand things can go on without me, but I just can't open on that day.

THE COURT: Oh, openings.

MS. ALLON: Yeah. I just -- so that's why, you know, if it takes us three days to pick a jury and then that's the day that we're at openings, that's going to be a problem for me.

THE COURT: Okay. You're not here on the 31st and the 1st?

MS. ALLON: I'm going to come back for the 1st. I'm going to make it back.

THE COURT: On the 1st?

MS. ALLON: Yes.

THE COURT: Oh. So maybe we'll do openings on the 1st.

MS. ALLON: Okay.

MR. SLATER: You'll leave your family for this? Don't do that.

MS. ALLON: I will leave my family, yes. It's okay. I will be back on the 1st. I would prefer not to --

THE COURT: Or you can all just settle and we would just allow her to go to the wedding and enjoy herself.

Okay. So what else did I want to say? Oh, we're going to try the case in my other courtroom. I've decided. So I have a courtroom over in 3D. I think it's just going to be

more accommodating, particularly to the attorneys. There's conference rooms that we can use outside the courtroom. And I just -- I think it's probably better suited for a trial of this size.

So I think I told you, I'm going to equip it with iPads. We're working on that. And I'm going to equip it with phones. That's where we'll do our sidebars, at tables, at the tables. So that's going to take some time to set up, so I wanted to mention that, that we'll be in 3D.

I probably will have you folks back for argument again on just, you know, I'm fussing with, you know, the claims and the theories and the damages and trying to put it all together in a comprehensive format to get my head around it.

Jury charges, where are you all with those?

MR. SLATER: I think --

THE COURT: I think that some of that will then depend upon my rulings and how I see the case.

MR. OSTFELD: Your Honor, I believe that the supplemental letters or briefing on the issue of the Esperanto jury instruction and whether it can be one instruction or it has to be jurisdiction-specific, we've submitted that.

THE COURT: Yeah.

MR. OSTFELD: If Your Honor would like to hear argument on that, we can certainly schedule that.

THE COURT: Yeah. I've looked at the issue. I have

in my head I think what I'm going to do, but I'll look at it more closely.

MR. OSTFELD: Okay.

THE COURT: Yeah. But where are you on the jury charges? You starting to work on them?

MR. SLATER: They were prepared and then I --

MR. OSTFELD: They were submitted, I believe --

MR. SLATER: They were submitted, but they're being reworked heavily.

MR. OSTFELD: -- with the original final pretrial order. I know that we'll be revising the final pretrial order.

THE COURT: Yeah.

MR. SLATER: I think --

MR. OSTFELD: If Your Honor provides guidance on the Esperanto issue, we may then be able to -- I mean, right now we have two completely different sets of jury instructions because one of them is sort of an omnibus set of instructions, and the defense side is a state-specific set of instructions for each state.

MR. SLATER: Right. Question for Your Honor.

MR. STANOCH: Your Honor, just on the instructions, I agree with what Mr. Ostfeld said. I just add that they, and I don't mean this pejoratively, their position is every state, every element needs a separate instruction. We didn't do an Esperanto. We grouped them based on the similarity of the

states, right? We didn't just merge everything into one. We said state A and B say the same thing under the law. So we said that's one charge. And we did that in groups. So that's really the difference. And if Your Honor gives us guidance that that's okay in some respects or others, I think we can work through the instructions.

THE COURT: Okay. I will, either through my law clerk or a text order, I'll do it. Or I'll have my law clerk reach out to you and let you know which one I prefer, and then I can rule on the record when we next meet.

But I do think I'm going to want oral argument on this whole, you know, the issue that's been, you know, gnawing --

MR. SLATER: The warranty issue?

THE COURT: -- gnawing at me, the damages and, you know, what the plaintiff can and can't argue to the jury. That will depend upon the briefing that I get from you all.

Because I do think that that will -- I think it really will form the complexion of the case and how it's presented to the jury, because I think you both are at such different ends of the spectrum on that.

Okay. So once I get the briefing, you'll hear from me.

MS. BROWN: Great. Thank you.

THE COURT: And I'll probably have you all back.

MS. BROWN: Thank you.

THE COURT: Okay.

MS. BROWN: Thanks, Your Honor.

MR. SLATER: I have a question.

Did Your Honor have any issue with us using paper exhibits or is it expected to be electronic?

THE COURT: I want everything electronic.

MR. SLATER: Okay. That's -- because Judge Kugler had the same approach, so I just wanted --

THE COURT: Paper or electronic?

MR. SLATER: Electronic.

THE COURT: Electronic, yeah. That's why I want the jurors to have iPads.

MR. SLATER: Okay.

THE COURT: And we'll figure out. I have not done it ever that way.

MS. BROWN: Me either.

MR. SLATER: I have not either.

MS. BROWN: I haven't either.

THE COURT: My colleagues have, and they really say great -- it works really well. And I think a case like this, it's --

MR. SLATER: I'm scared to death of it.

THE COURT: I know. But it's required. You can't have a jury swimming in paper like this.

MS. BROWN: Yeah.

THE COURT: So, yeah. Did you want to say something?

MS. BROWN: No. No. I was rising to say thank you.

THE COURT: All right. Good to see you all.

MR. SLATER: Thank you, Your Honor. Have a nice night.

MS. BROWN: Thanks, Judge.

(Proceedings concluded at 4:35 p.m.)

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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/John J. Kurz, RDR-RMR-CRR-CRC September 21, 2024

Court Reporter/Transcriber